

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 484**

[CMS–1672–F]

RIN 0938–AT01

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** 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, 2018. This rule also: Updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the third 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 calendar year (CY) 2012 and CY 2014; and discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CY 2014 through CY 2017. In addition, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP). We are not finalizing the implementation of the Home Health Groupings Model (HHGM) in this final rule.

DATES: These regulations are effective on January 1, 2018.**FOR FURTHER INFORMATION CONTACT:**

For general information about the Home Health Prospective Payment System (HH PPS), please send your inquiry via email to:

HomehealthPolicy@cms.hhs.gov.

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

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

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the internet on the CMS Web site at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html.

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Acronyms

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

- ACH LOS Acute Care Hospital Length of Stay
- ADL Activities of Daily Living
- AM–PAC Activity Measure for Post-Acute Care
- APR DRG All-Patient Refined Diagnosis-Related Group
- APU Annual Payment Update
- ASPE Assistant Secretary for Planning and Evaluation
- BBA Balanced Budget Act of 1997, Public Law 105–33
- BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
- BIMS Brief Interview for Mental Status
- BLS Bureau of Labor Statistics
- CAD Coronary Artery Disease
- CAH Critical Access Hospital
- CAM Confusion Assessment Method
- CARE Continuity Assessment Record and Evaluation
- CASPER Certification and Survey Provider Enhanced Reports
- CBSA Core-Based Statistical Area
- CCN CMS Certification Number
- CHF Congestive Heart Failure
- CMI Case-Mix Index
- CMP Civil Money Penalty
- CMS Centers for Medicare & Medicaid Services
- CoPs Conditions of Participation
- COPD Chronic Obstructive Pulmonary Disease
- CVD Cardiovascular Disease
- CY Calendar Year
- DM Diabetes Mellitus
- DRA Deficit Reduction Act of 2005, Public Law 109–171, enacted February 8, 2006
- DRG Diagnosis-Related Group
- DTI Deep Tissue Injury
- EOC End of Care
- FDL Fixed Dollar Loss
- FI Fiscal Intermediaries
- FR Federal Register
- FY Fiscal Year
- HAVEN Home Assessment Validation and Entry System
- HCC Hierarchical Condition Categories
- HCIS Health Care Information System
- HH Home Health
- HHA Home Health Agency

HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey

HH PPS Home Health Prospective Payment System

HHGM Home Health Groupings Model

HHQRP Home Health Quality Reporting Program

HHRG Home Health Resource Group

HHVBP Home Health Value-Based Purchasing

HIPPS Health Insurance Prospective Payment System

HVBP Hospital Value-Based Purchasing

IADL Instrumental Activities of Daily Living

ICD-9-CM International Classification of Diseases, Ninth Revision, Clinical Modification

ICD-10-CM International Classification of Diseases, Tenth Revision, Clinical Modification

IH Inpatient Hospitalization

IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113-185)

IPPS [Acute Care Hospital] Inpatient Prospective Payment System

IPR Interim Performance Report

IRF Inpatient Rehabilitation Facility

IRF-PAI IRF Patient Assessment Instrument

IV Intravenous

LCDS LTCH CARE Data Set

LEF Linear Exchange Function

LTCH Long-Term Care Hospital

LUPA Low-Utilization Payment Adjustment

MACRA Medicare Access and CHIP Reauthorization Act of 2015

MAP Measure Applications Partnership

MDS Minimum Data Set

MFP Multifactor productivity

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, enacted December 8, 2003

MSA Metropolitan Statistical Area

MSS Medical Social Services

NQF National Quality Forum

NQS National Quality Strategy

NRS Non-Routine Supplies

OASIS Outcome and Assessment Information Set

OBRA Omnibus Budget Reconciliation Act of 1987, Public Law 100-2-3, enacted December 22, 1987

OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Public Law 105-277, enacted October 21, 1998

OES Occupational Employment Statistics

OIG Office of Inspector General

OLS Ordinary Least Squares

OT Occupational Therapy

OMB Office of Management and Budget

PAC Post-Acute Care

PAC-PRD Post-Acute Care Payment Reform Demonstration

PAMA Protecting Access to Medicare Act of 2014

PEP Partial Episode Payment Adjustment

PHQ-2 Patient Health Questionnaire-2

PPOC Primary Point of Contact

PPS Prospective Payment System

PRA Paperwork Reduction Act

PRRB Provider Reimbursement Review Board

PT Physical Therapy

PY Performance Year

QAP Quality Assurance Plan

QIES Quality Improvement Evaluation System

QRP Quality Reporting Program

RAP Request for Anticipated Payment

RF Renal Failure

RFA Regulatory Flexibility Act, Public Law 96-354

RHHIs Regional Home Health Intermediaries

RIA Regulatory Impact Analysis

ROC Resumption of Care

SAF Standard Analytic File

SLP Speech-Language Pathology

SN Skilled Nursing

SNF Skilled Nursing Facility

SOC Start of Care

SSI Surgical Site Infection

TEP Technical Expert Panel

TPS Total Performance Score

UMRA Unfunded Mandates Reform Act of 1995

VAD Vascular Access Device

VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This final rule updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2018, as required under section 1895(b) of the Social Security Act (the Act). This final rule also updates the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2018 and implements a 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014, under the authority of section 1895(b)(3)(B)(iv) of the Act. Additionally, this rule finalizes changes to the Home Health Value Based Purchasing (HHVBP) Model under the authority of section 1115A of the Act, and Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act. We are not finalizing the implementation of the Home Health Groupings Model (HHGM) in this final rule. We received a number of comments from the public that we would like to take into further consideration.

B. Summary of the Major Provisions

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B. of this final rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner. Also in section III.B. of this final rule, as finalized in the CY

2016 HH PPS final rule (80 FR 68624), we are implementing a reduction to the national, standardized 60-day episode payment rate for CY 2018 of 0.97 percent to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. In section III.C. of this final rule, we update the payment rates under the HH PPS by 1 percent for CY 2018 in accordance with section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015) which amended section 1895(b)(3)(B) of the Act. Additionally, section III.C. of this final rule, updates the CY 2018 home health wage index using FY 2014 hospital cost report data. In section III.D. of this final rule, we note that the fixed-dollar loss ratio remains 0.55 for CY 2018 to pay up to, but no more than, 2.5 percent of total payments as outlier payments, as required by section 1895(b)(5)(A) of the Act.

In section IV of this final rule, we are finalizing changes to the Home Health Value-Based Purchasing (HHVBP) Model implemented January 1, 2016. We are amending the definition of “applicable measure” to mean a measure for which a competing HHA has provided a minimum of 40 completed surveys for Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) measures, beginning with Performance Year (PY) 1, for purposes of receiving a performance score for any of the HHCAHPS measures, and for PY 3 and subsequent years, we are finalizing the removal of the Outcome and Assessment Information Set (OASIS)-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures.

In section V. of this final rule, we are finalizing updates to the Home Health Quality Reporting Program, including: The replacement of one quality measure and the adoption of two new quality measures, data submission requirements, exception and extension requirements, and reconsideration and appeals procedures. We have also finalized the removal of 235 data elements from 33 current OASIS items, effective with all HHA assessments on or after January 1, 2019. We are not finalizing the standardized patient assessment data elements that we proposed to adopt for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

| Provision description | Costs | Transfers |
|--|--|--|
| CY 2018 HH PPS Payment Rate Update. CY 2018 HHVBP Model | | The overall economic impact of the HH PPS payment rate update is an estimated –\$80 million (–0.4 percent) in payments to HHAs. The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes finalized in this final rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model. |
| CY 2019 HH QRP | The overall economic impact of the HH QRP changes is a savings to HHAs of an estimated \$146.0 million, beginning January 1, 2019. | |

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 home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

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

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount 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 home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

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

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

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final

rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and 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 home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-

for-reporting requirement was implemented on January 1, 2007.

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

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018. Section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and

service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6; 7 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

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

C. Updates to the Home Health Prospective Payment System

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

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth

year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

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

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

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we must phase in any adjustment over a 4-year

period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of \$80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the second year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

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

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). We also finalized changes to the methodology used to calculate outlier payments under the authority of

section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

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

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

The research for the Report to Congress, released in December 2014, consisted of extensive analysis of both survey and administrative data. The CMS-developed surveys were given to physicians who referred vulnerable patient populations to Medicare home health and to Medicare-certified HHAs.² The response rates were 72 percent and 59 percent for the HHA and physician surveys, respectively. The results of the survey revealed that over 80 percent of respondent HHAs and over 90 percent of respondent physicians reported that access to home health care for Medicare fee-for-service beneficiaries in their local area was excellent or good. When survey respondents reported access issues, specifically their inability to place or admit Medicare fee-for-service patients into home health, the most

common reason reported (64 percent of respondent HHAs surveyed) was that the patients did not qualify for the Medicare home health benefit. HHAs and physicians also cited family or caregiver issues as an important contributing factor in the inability to admit or place patients. Only 17.2 percent of HHAs and 16.7 percent of physicians reported insufficient payment as an important contributing factor in the inability to admit or place patients. The results of the CMS-conducted surveys suggested that CMS’ ability to improve access for certain vulnerable patient populations through payment policy may be limited. However, we are able to revise the case-mix system to minimize differences in payment that could potentially be serving as a barrier to receiving care. In the near future, we intend to better align payment with resource use so that it reduces HHAs’ financial incentives to select certain patients over others.

We also performed an analysis of Medicare administrative data (CY 2010 Medicare claims and cost report data) and calculated margins for episodes of care. This was done because margin differences associated with patient clinical and social characteristics can indicate whether financial incentives exist in the current HH PPS to provide home health care for certain types of patients over others. Lower margins, if systematically associated with care for vulnerable patient populations, may indicate financial disincentives for HHAs to admit these patients, potentially creating access to care issues. The findings from the data analysis found that certain patient characteristics appear to be strongly associated with margin levels, and thus may create financial incentives to select certain patients over others. Margins were estimated to be lower for patients who required parenteral nutrition, who had traumatic wounds or ulcers, or required substantial assistance in bathing. For example, in CY 2010, episodes for patients with parenteral nutrition were, on average, associated with a \$178.53 lower margin than episodes for patients without parenteral nutrition. Given that these variables are already included in the HH PPS case-mix system, the results indicated that modifications to the way the current case-mix system accounts for resource use differences may be needed to mitigate any financial incentives to select certain patients over others. Margins were also lower for beneficiaries who were admitted after acute or post-acute stays or who had certain poorly-controlled clinical

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

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

conditions, such as poorly controlled pulmonary disorders, indicating that accounting for additional patient characteristic variables in the HH PPS case-mix system may also reduce financial incentives to select certain types of patients over others. More information on the results from the home health study required by section 3131(d) of the Affordable Care Act can be found in the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations” available at <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>.

Section 3131(d)(5) of the Affordable Care Act authorized the Secretary to determine whether it would be appropriate to conduct a Medicare demonstration project based on the result of the home health study. If the Secretary determined it was appropriate to conduct the demonstration project under this subsection, the Secretary was to conduct the project for a 4-year period beginning not later than January 1, 2015. We did not determine that it was appropriate to conduct a demonstration project based on the findings from the home health study. Rather, the findings from the home health study suggested that follow-on

work should be conducted to better align payments with costs under the authority of section 1895 of the Act.

In addition to the findings from the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations,” concerns have also been raised about the use of therapy thresholds in the current payment system. Under the current payment system, HHAs receive higher payments for providing more therapy visits once certain thresholds are reached. As a result, the average number of therapy visits per 60-day episode of care have increased since the implementation of the HH PPS, while the number of skilled nursing and home health aide visits have decreased over the same time period (82 FR 35280 (Figure 3)). A study examining an option of using predicted, rather than actual, therapy visits in the home health found that in 2013, 58 percent of home health episodes included some therapy services, and these episodes accounted for 72 percent of all Medicare home health payments.³ Figure 1, from that

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

study, demonstrates that the percentage of episodes, and the average episode payment by the number of therapy visits for episodes with at least one therapy visit in 2013 increased sharply in therapy provision just over payment thresholds at 6, 7, and 16. According to the study, the presence of sharp increases in the percentage of episodes just above payment thresholds suggests a response to financial incentives in the home health payment system. Similarly, between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, compared with a 1 percent increase in the number of episodes with 5 or fewer therapy visits.⁴ CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35277 through 35278 (Table 2)).

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

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

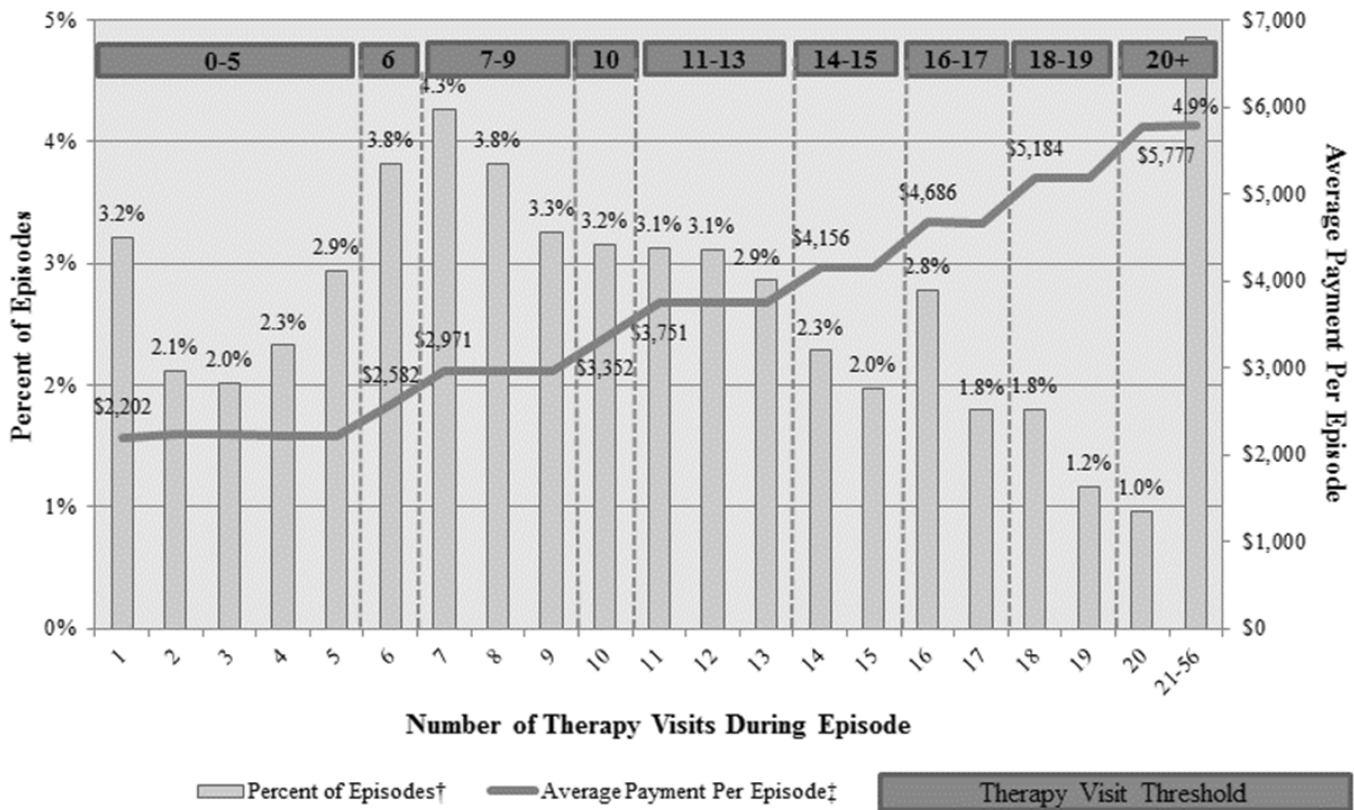


Figure 1 suggests that HHAs may be responding to financial incentives in the home health payment system when making care plan decisions. Additionally, an investigation into the therapy practices of the four largest publically-traded home health companies, conducted by the Senate Committee on Finance in 2010, found that three out of the four companies investigated “encouraged therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns”.⁵ The Senate Committee on Finance investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize reimbursement under the therapy threshold models (both the original 10-visit threshold model and under the revised thresholds implemented in the CY 2008 HH PPS final rule (72 FR 49762)). The report noted that, under the HH PPS, HHAs have broad discretion over the number

of therapy visits to provide patients, and therefore, have control of the single-largest variable in determining reimbursement and overall margins. The report recommended that CMS closely examine a future payment approach that focuses on patient well-being and health characteristics, rather than the numerical utilization measures.

MedPAC also continues to recommend the removal of the therapy thresholds used for determining payment from the HH PPS, as it believes that such thresholds run counter to the goals of a prospective payment system, create financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and incentivize unnecessary therapy utilization. For the average HHA, according to MedPAC, the increase in payment for therapy visits rises faster than costs, resulting in financial incentives for HHAs to overprovide therapy services.⁶ HHAs that provide

more therapy episodes tend to be more profitable and this higher profitability and rapid growth in the number of therapy episodes suggest that financial incentives are causing agencies to favor therapy services when possible.⁷ Eliminating therapy as a payment factor will base home health payment solely on patient characteristics, which is a more patient-focused approach to payment, as recommended by both MedPAC and previously by the Senate Committee on Finance.

After considering the findings from the Report to Congress and recommendations from MedPAC and the Senate Committee on Finance, CMS, along with our contractor, conducted additional research on ways to improve the payment accuracy under the current payment system. Exploring all options and different models ultimately led us to further develop the Home Health Groupings Model (HHGM). As discussed in the CY 2018 HH PPS proposed rule (82 FR 35294), we shared

⁵ Committee on Finance, United States Senate. Staff Report on Home Health and the Medicare Therapy Threshold. Washington, DC, 2011. Accessed on March 28, 2017 at https://www.finance.senate.gov/imo/media/doc/Home_Health_Report_Final4.pdf.

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

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

the analysis and development of the HHGM with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744), in a detailed technical report posted on the CMS Web site in December 2016 (followed by additional technical and clinical expert panels) and a National Provider Call in January 2017. The HHGM uses 30-day periods, rather than 60-day episodes, and relies more heavily on clinical characteristics and other patient information (for example, principal diagnosis, functional level, comorbid conditions, admission source, and timing) to place patients into meaningful payment categories, rather than the current therapy-driven system, which are the major differences between the current system and the HHGM.

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

In the July 28, 2017 **Federal Register** (82 FR 35270 through 35393), we published the proposed rule titled “Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements”. We received approximately 1,346 timely comments from the public, including comments from home health agencies, national and state provider associations, patient and other advocacy organizations, nurses, and physical therapists. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

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

In the CY 2018 HH PPS proposed rule (82 FR 35277), we provided a summary of analysis on fiscal year (FY) 2015 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 statistics and trends that included HHA claims data through CY 2016. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry

with periodic updates on our analysis in rulemaking and announcements on the HHA Center Web page at <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

The following is a summary of the comments received on the analysis of HHA cost report and utilization data and our responses.

Comment: A commenter noted that it may come as no surprise that payments exceed costs by 21 percent, given that Medicare payment for home health is statutorily required to be based on a prospective payment system and the industry is now 90 percent for-profit, with incentives to admit only the most profitable cases. The commenter went on to state that home health payments from Medicare Advantage (MA) plans are inadequate and that HHAs subsidize low payments from MA plans with payments for fee-for-service patients. The commenter further noted that the number of patients coming into home health care from the community (rather than following an acute or post-acute care stay) has risen in response to deliberate Medicare and public health effort to keep patients out of the hospital. Similar comments from MedPAC stated that CMS’s review of utilization is consistent with the Commission’s findings on access to care, and the analysis of the cost and utilization data in the proposed rule underscores the Commission’s long-standing concern that the Patient Protection and Affordable Care Act (PPACA) rebasing provision would not adequately reduce payments.

Response: We thank the commenters for their feedback on the HHA cost and utilization data presented in the proposed rule. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry with periodic updates on our analysis in rulemaking or announcements on the HHA Center Web page at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

Comment: A commenter questioned whether CMS did any trimming to the cost report data used to populate Table 2 in the CY 2018 HH PPS proposed rule and whether NRS costs were excluded from this calculation.

Response: As we noted in the CY 2018 HH PPS proposed rule (82 FR 35277), to determine the 2015 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2015 cost reports by size, facility type, and urban/rural location so the costs per

visit were nationally representative according to 2015 claims data. The 2015 average number of visits was taken from 2015 claims data (82 FR 35277). Because CMS currently pays for NRS using a separate conversion factor, NRS costs were not included in Table 2 as the national, standardized 60-day episode payment amount only reflects the cost of care related to skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services. The payment for NRS is calculated through the NRS conversion factor, multiplied by the weights for the six severity levels.

B. CY 2018 HH PPS Case-Mix Weights

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

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

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2015 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2016 home health claims data, are shown in Table 2. 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 2—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

| | Episode number within sequence of adjacent episodes Therapy visits EQUATION: | 1 or 2 0–13 1 | 1 or 2 14+ 2 | 3+ 0–13 3 | 3+ 14+ 4 |
|-----------------------------|--|---------------------|--------------------|-----------------|----------------|
| CLINICAL DIMENSION | | | | | |
| 1 | Primary or Other Diagnosis = Blindness/Low Vision | | | | |
| 2 | Primary or Other Diagnosis = Blood disorders | | 1 | | |
| 3 | Primary or Other Diagnosis = Cancer, selected benign neoplasms | | 4 | | 4 |
| 4 | Primary Diagnosis = Diabetes | | 3 | | |
| 5 | Other Diagnosis = Diabetes | 1 | | | |
| 6 | Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3—Stroke. | 2 | 16 | 1 | 10 |
| 7 | Primary or Other Diagnosis = Dysphagia AND M1030 (Therapy at home) = 3 (Enteral). | 1 | 5 | | 9 |
| 8 | Primary or Other Diagnosis = Gastrointestinal disorders | | | | 2 |
| 9 | Primary or Other Diagnosis = Gastrointestinal disorders AND M1630 (ostomy)= 1 or 2. | | 7 | | |
| 10 | Primary or Other Diagnosis = Gastrointestinal disorders AND Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis, OR Neuro 2—Peripheral neurological disorders, OR Neuro 3—Stroke, OR Neuro 4—Multiple Sclerosis. | | | | |
| 11 | Primary or Other Diagnosis = Heart Disease OR Hypertension | 1 | 3 | | 2 |
| 12 | Primary Diagnosis = Neuro 1—Brain disorders and paralysis | 3 | 9 | 6 | 9 |
| 13 | Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis AND M1840 (Toilet transfer) = 2 or more. | | 4 | | 4 |
| 14 | Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis OR Neuro 2—Peripheral neurological disorders AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3. | 2 | 4 | 2 | 4 |
| 15 | Primary or Other Diagnosis = Neuro 3—Stroke | 3 | 9 | 2 | 4 |
| 16 | Primary or Other Diagnosis = Neuro 3—Stroke AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3. | | 2 | | |
| 17 | Primary or Other Diagnosis = Neuro 3—Stroke AND M1860 (Ambulation) = 4 or more. | | | | |
| 18 | Primary or Other Diagnosis = Neuro 4—Multiple Sclerosis AND AT LEAST ONE OF THE FOLLOWING: M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more OR M1850 (Transferring) = 2 or more OR M1860 (Ambulation) = 4 or more. | 3 | 7 | 5 | 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. | 7 | 1 | 7 | |
| 20 | Primary or Other Diagnosis = Ortho 1—Leg OR Ortho 2—Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral). | 3 | | 3 | 7 |
| 21 | Primary or Other Diagnosis = Psych 1—Affective and other psychoses, depression. | | | | |
| 22 | Primary or Other Diagnosis = Psych 2—Degenerative and other organic psychiatric disorders. | | | | |
| 23 | Primary or Other Diagnosis = Pulmonary disorders | | 2 | | 1 |
| 24 | Primary or Other Diagnosis = Pulmonary disorders AND M1860 (Ambulation) = 1 or more. | | | | |
| 25 | Primary Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications. | 3 | 17 | 6 | 17 |
| 26 | Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications. | 6 | 14 | 7 | 14 |
| 27 | Primary or Other Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications OR Skin 2—Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral). | 2 | | | |
| 28 | Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions | 2 | 16 | 8 | 18 |
| 29 | Primary or Other Diagnosis = Tracheostomy | 2 | 17 | | 17 |
| 30 | Primary or Other Diagnosis = Urostomy/Cystostomy | | 17 | | 12 |
| 31 | M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral) | | 15 | 5 | 15 |
| 32 | M1030 (Therapy at home) = 3 (Enteral) | | 16 | | 6 |
| 33 | M1200 (Vision) = 1 or more | | | | |
| 34 | M1242 (Pain)= 3 or 4 | 3 | | 2 | |
| 35 | M1311 = Two or more pressure ulcers at stage 3 or 4 | 4 | 6 | 4 | 6 |
| 36 | M1324 (Most problematic pressure ulcer stage) = 1 or 2 | 4 | 19 | 7 | 17 |
| 37 | M1324 (Most problematic pressure ulcer stage)= 3 or 4 | 9 | 31 | 10 | 25 |
| 38 | M1334 (Stasis ulcer status) = 2 | 4 | 13 | 8 | 13 |
| 39 | M1334 (Stasis ulcer status) = 3 | 7 | 17 | 9 | 17 |
| 40 | M1342 (Surgical wound status) = 2 | 2 | 7 | 6 | 13 |
| 41 | M1342 (Surgical wound status) = 3 | | 6 | 5 | 10 |
| 42 | M1400 (Dyspnea) = 2, 3, or 4 | 1 | 1 | | |
| 43 | M1620 (Bowel Incontinence) = 2 to 5 | | 3 | | 2 |
| 44 | M1630 (Ostomy) = 1 or 2 | 4 | 11 | 2 | 8 |
| 45 | M2030 (Injectable Drug Use) = 0, 1, 2, or 3 | | | | |
| FUNCTIONAL DIMENSION | | | | | |
| 46 | M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3 | 1 | | | |
| 47 | M1830 (Bathing) = 2 or more | 6 | 5 | 6 | 2 |
| 48 | M1840 (Toilet transferring) = 2 or more | | 1 | | |

TABLE 2—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

| | | | | | |
|----------|--|---|-------|---|-------|
| 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 | 7 | 7 |

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

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

In updating the four-equation model for CY 2018, using 2016 home health claims data (the last update to the four-equation model for CY 2017 used CY 2015 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2015 and CY 2016. The CY 2018 four-equation model resulted in 120 point-giving variables being used in the model (as compared to the 124 variables for the CY 2017 recalibration). There were 8 variables that were added to the model and 12 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2017 and the four-equation model for CY 2018, the points for 14 variables increased in the CY 2018 four-equation model and

the points for 48 variables decreased in the CY 2018 4-equation model. There were 50 variables with the same point values.

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

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

Then, we divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.⁸ Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2018 four-equation model points are shown in Table 3.

TABLE 3—CY 2018 CLINICAL AND FUNCTIONAL THRESHOLDS

| | | 1st and 2nd episodes | | 3rd+ episodes | | All episodes |
|--|----------------|------------------------|-------------------------|------------------------|-------------------------|--------------------|
| | | 0 to 13 therapy visits | 14 to 19 therapy visits | 0 to 13 therapy visits | 14 to 19 therapy visits | 20+ therapy visits |
| Grouping Step | | 1 | 2 | 3 | 4 | 5 |
| Equations used to calculate points (see Table 1) | | 1 | 2 | 3 | 4 | (2&4) |
| Dimension | Severity Level | | | | | |
| Clinical | C1 | 0 to 1 | 0 to 1 | 0 to 1 | 0 to 1 | 0 to 3 |
| | C2 | 2 to 3 | 2 to 7 | 2 | 2 to 9 | 4 to 16 |
| | C3 | 4+ | 8+ | 3+ | 10+ | 17+ |
| Functional | F1 | 0 to 13 | 0 to 7 | 0 to 6 | 0 to 2 | 0 to 2 |
| | F2 | 14 | 8 to 15 | 7 to 10 | 3 to 7 | 3 to 6 |
| | F3 | 15+ | 16+ | 11+ | 8+ | 7+ |

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 4 shows the regression coefficients for the variables in the payment regression model updated with CY 2016 home health claims data. The R-squared value for the payment regression model is

⁸ For Step 1, 45.3 percent of episodes were in the medium functional level (All with score 14).

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

For Step 2.2, 81.9 percent of episodes were in the low functional level (Most with score 2).

For Step 3, 46.3 percent of episodes were in the medium functional level (Most with score 10).

For Step 4, 48.7 percent of episodes were in the medium functional level (Most with score 5 or 6).

0.5095 (an increase from 0.4919 for the CY 2017 recalibration).

TABLE 4—PAYMENT REGRESSION MODEL

| | Payment regression from 4-equation model for CY 2018 |
|---|--|
| Step 1, Clinical Score Medium | \$24.58 |
| Step 1, Clinical Score High | 54.24 |
| Step 1, Functional Score Medium | 72.76 |
| Step 1, Functional Score High | 107.48 |
| Step 2.1, Clinical Score Medium | 48.81 |
| Step 2.1, Clinical Score High | 135.99 |
| Step 2.1, Functional Score Medium | 31.51 |
| Step 2.1, Functional Score High | 57.73 |
| Step 2.2, Clinical Score Medium | 39.37 |
| Step 2.2, Clinical Score High | 194.18 |
| Step 2.2, Functional Score Medium | 21.53 |
| Step 2.2, Functional Score High | 56.25 |
| Step 3, Clinical Score Medium | 17.07 |
| Step 3, Clinical Score High | 95.93 |
| Step 3, Functional Score Medium | 59.15 |
| Step 3, Functional Score High | 90.40 |
| Step 4, Clinical Score Medium | 80.09 |
| Step 4, Clinical Score High | 263.75 |
| Step 4, Functional Score Medium | 27.97 |
| Step 4, Functional Score High | 62.20 |
| Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits | 512.27 |
| Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits | 523.60 |
| Step 3, 3rd+ Episodes, 0–13 Therapy Visits | – 72.22 |
| Step 4, All Episodes, 20+ Therapy Visits | 907.99 |
| Intercept | 389.35 |

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

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

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14 to 15 therapy visits

are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC’s concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.⁹

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/late 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 to 5 to 14 to 15 therapy visits, and from 14 to 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 and 5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7 to 9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.¹⁰ This last step creates the final CY 2018 case-mix weights shown in Table 5.

⁹ Medicare Payment Advisory Commission (MedPAC). *Report to the Congress: Medicare Payment Policy*. March 2011, p. 176.

¹⁰ 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 5—CY 2018 CASE-MIX PAYMENT WEIGHTS

| Pay group | Description | Clinical and functional levels (1 = Low; 2 = Medium; 3 = High) | CY 2018 weight |
|-----------|---|---|----------------|
| 10111 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C1F1S1 | 0.5595 |
| 10112 | 1st and 2nd Episodes, 6 Therapy Visits | C1F1S2 | 0.6911 |
| 10113 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C1F1S3 | 0.8227 |
| 10114 | 1st and 2nd Episodes, 10 Therapy Visits | C1F1S4 | 0.9543 |
| 10115 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C1F1S5 | 1.0859 |
| 10121 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C1F2S1 | 0.6640 |
| 10122 | 1st and 2nd Episodes, 6 Therapy Visits | C1F2S2 | 0.7832 |
| 10123 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C1F2S3 | 0.9025 |
| 10124 | 1st and 2nd Episodes, 10 Therapy Visits | C1F2S4 | 1.0217 |
| 10125 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C1F2S5 | 1.1409 |
| 10131 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C1F3S1 | 0.7139 |
| 10132 | 1st and 2nd Episodes, 6 Therapy Visits | C1F3S2 | 0.8302 |
| 10133 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C1F3S3 | 0.9466 |
| 10134 | 1st and 2nd Episodes, 10 Therapy Visits | C1F3S4 | 1.0629 |
| 10135 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C1F3S5 | 1.1792 |
| 10211 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C2F1S1 | 0.5948 |
| 10212 | 1st and 2nd Episodes, 6 Therapy Visits | C2F1S2 | 0.7325 |
| 10213 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C2F1S3 | 0.8703 |
| 10214 | 1st and 2nd Episodes, 10 Therapy Visits | C2F1S4 | 1.0080 |
| 10215 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C2F1S5 | 1.1457 |
| 10221 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C2F2S1 | 0.6994 |
| 10222 | 1st and 2nd Episodes, 6 Therapy Visits | C2F2S2 | 0.8247 |
| 10223 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C2F2S3 | 0.9500 |
| 10224 | 1st and 2nd Episodes, 10 Therapy Visits | C2F2S4 | 1.0753 |
| 10225 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C2F2S5 | 1.2007 |
| 10231 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C2F3S1 | 0.7493 |
| 10232 | 1st and 2nd Episodes, 6 Therapy Visits | C2F3S2 | 0.8717 |
| 10233 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C2F3S3 | 0.9941 |
| 10234 | 1st and 2nd Episodes, 10 Therapy Visits | C2F3S4 | 1.1166 |
| 10235 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C2F3S5 | 1.2390 |
| 10311 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C3F1S1 | 0.6374 |
| 10312 | 1st and 2nd Episodes, 6 Therapy Visits | C3F1S2 | 0.7902 |
| 10313 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C3F1S3 | 0.9429 |
| 10314 | 1st and 2nd Episodes, 10 Therapy Visits | C3F1S4 | 1.0957 |
| 10315 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C3F1S5 | 1.2484 |
| 10321 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C3F2S1 | 0.7420 |
| 10322 | 1st and 2nd Episodes, 6 Therapy Visits | C3F2S2 | 0.8823 |
| 10323 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C3F2S3 | 1.0227 |
| 10324 | 1st and 2nd Episodes, 10 Therapy Visits | C3F2S4 | 1.1630 |
| 10325 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C3F2S5 | 1.3034 |
| 10331 | 1st and 2nd Episodes, 0 to 5 Therapy Visits | C3F3S1 | 0.7919 |
| 10332 | 1st and 2nd Episodes, 6 Therapy Visits | C3F3S2 | 0.9293 |
| 10333 | 1st and 2nd Episodes, 7 to 9 Therapy Visits | C3F3S3 | 1.0668 |
| 10334 | 1st and 2nd Episodes, 10 Therapy Visits | C3F3S4 | 1.2042 |
| 10335 | 1st and 2nd Episodes, 11 to 13 Therapy Visits | C3F3S5 | 1.3417 |
| 21111 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C1F1S1 | 1.2176 |
| 21112 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C1F1S2 | 1.3807 |
| 21113 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C1F1S3 | 1.5439 |
| 21121 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C1F2S1 | 1.2601 |
| 21122 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C1F2S2 | 1.4213 |
| 21123 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C1F2S3 | 1.5826 |
| 21131 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C1F3S1 | 1.2955 |
| 21132 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C1F3S2 | 1.4600 |
| 21133 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C1F3S3 | 1.6244 |
| 21211 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C2F1S1 | 1.2835 |
| 21212 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C2F1S2 | 1.4598 |
| 21213 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C2F1S3 | 1.6361 |
| 21221 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C2F2S1 | 1.3260 |
| 21222 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C2F2S2 | 1.5004 |
| 21223 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C2F2S3 | 1.6748 |
| 21231 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C2F3S1 | 1.3614 |
| 21232 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C2F3S2 | 1.5390 |
| 21233 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C2F3S3 | 1.7166 |
| 21311 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C3F1S1 | 1.4012 |
| 21312 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C3F1S2 | 1.6188 |
| 21313 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C3F1S3 | 1.8364 |
| 21321 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C3F2S1 | 1.4437 |
| 21322 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C3F2S2 | 1.6594 |

TABLE 5—CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

| Pay group | Description | Clinical and functional levels (1 = Low; 2 = Medium; 3 = High) | CY 2018 weight |
|-----------|---|---|----------------|
| 21323 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C3F2S3 | 1.8751 |
| 21331 | 1st and 2nd Episodes, 14 to 15 Therapy Visits | C3F3S1 | 1.4791 |
| 21332 | 1st and 2nd Episodes, 16 to 17 Therapy Visits | C3F3S2 | 1.6981 |
| 21333 | 1st and 2nd Episodes, 18 to 19 Therapy Visits | C3F3S3 | 1.9170 |
| 22111 | 3rd+ Episodes, 14 to 15 Therapy Visits | C1F1S1 | 1.2328 |
| 22112 | 3rd+ Episodes, 16 to 17 Therapy Visits | C1F1S2 | 1.3909 |
| 22113 | 3rd+ Episodes, 18 to 19 Therapy Visits | C1F1S3 | 1.5489 |
| 22121 | 3rd+ Episodes, 14 to 15 Therapy Visits | C1F2S1 | 1.2619 |
| 22122 | 3rd+ Episodes, 16 to 17 Therapy Visits | C1F2S2 | 1.4225 |
| 22123 | 3rd+ Episodes, 18 to 19 Therapy Visits | C1F2S3 | 1.5832 |
| 22131 | 3rd+ Episodes, 14 to 15 Therapy Visits | C1F3S1 | 1.3088 |
| 22132 | 3rd+ Episodes, 16 to 17 Therapy Visits | C1F3S2 | 1.4688 |
| 22133 | 3rd+ Episodes, 18 to 19 Therapy Visits | C1F3S3 | 1.6288 |
| 22211 | 3rd++ Episodes, 14 to 15 Therapy Visits | C2F1S1 | 1.2860 |
| 22212 | 3rd+ Episodes, 16 to 17 Therapy Visits | C2F1S2 | 1.4615 |
| 22213 | 3rd+ Episodes, 18 to 19 Therapy Visits | C2F1S3 | 1.6369 |
| 22221 | 3rd+ Episodes, 14 to 15 Therapy Visits | C2F2S1 | 1.3151 |
| 22222 | 3rd+ Episodes, 16 to 17 Therapy Visits | C2F2S2 | 1.4931 |
| 22223 | 3rd+ Episodes, 18 to 19 Therapy Visits | C2F2S3 | 1.6712 |
| 22231 | 3rd+ Episodes, 14 to 15 Therapy Visits | C2F3S1 | 1.3620 |
| 22232 | 3rd+ Episodes, 16 to 17 Therapy Visits | C2F3S2 | 1.5394 |
| 22233 | 3rd+ Episodes, 18 to 19 Therapy Visits | C2F3S3 | 1.7168 |
| 22311 | 3rd+ Episodes, 14 to 15 Therapy Visits | C3F1S1 | 1.4951 |
| 22312 | 3rd+ Episodes, 16 to 17 Therapy Visits | C3F1S2 | 1.6814 |
| 22313 | 3rd+ Episodes, 18 to 19 Therapy Visits | C3F1S3 | 1.8677 |
| 22321 | 3rd+ Episodes, 14 to 15 Therapy Visits | C3F2S1 | 1.5241 |
| 22322 | 3rd+ Episodes, 16 to 17 Therapy Visits | C3F2S2 | 1.7130 |
| 22323 | 3rd+ Episodes, 18 to 19 Therapy Visits | C3F2S3 | 1.9019 |
| 22331 | 3rd+ Episodes, 14 to 15 Therapy Visits | C3F3S1 | 1.5710 |
| 22332 | 3rd+ Episodes, 16 to 17 Therapy Visits | C3F3S2 | 1.7593 |
| 22333 | 3rd+ Episodes, 18 to 19 Therapy Visits | C3F3S3 | 1.9476 |
| 30111 | 3rd+ Episodes, 0 to 5 Therapy Visits | C1F1S1 | 0.4557 |
| 30112 | 3rd+ Episodes, 6 Therapy Visits | C1F1S2 | 0.6111 |
| 30113 | 3rd+ Episodes, 7 to 9 Therapy Visits | C1F1S3 | 0.7666 |
| 30114 | 3rd+ Episodes, 10 Therapy Visits | C1F1S4 | 0.9220 |
| 30115 | 3rd+ Episodes, 11 to 13 Therapy Visits | C1F1S5 | 1.0774 |
| 30121 | 3rd+ Episodes, 0 to 5 Therapy Visits | C1F2S1 | 0.5407 |
| 30122 | 3rd+ Episodes, 6 Therapy Visits | C1F2S2 | 0.6850 |
| 30123 | 3rd+ Episodes, 7 to 9 Therapy Visits | C1F2S3 | 0.8292 |
| 30124 | 3rd+ Episodes, 10 Therapy Visits | C1F2S4 | 0.9734 |
| 30125 | 3rd+ Episodes, 11 to 13 Therapy Visits | C1F2S5 | 1.1177 |
| 30131 | 3rd+ Episodes, 0 to 5 Therapy Visits | C1F3S1 | 0.5856 |
| 30132 | 3rd+ Episodes, 6 Therapy Visits | C1F3S2 | 0.7303 |
| 30133 | 3rd+ Episodes, 7 to 9 Therapy Visits | C1F3S3 | 0.8749 |
| 30134 | 3rd+ Episodes, 10 Therapy Visits | C1F3S4 | 1.0195 |
| 30135 | 3rd+ Episodes, 11 to 13 Therapy Visits | C1F3S5 | 1.1642 |
| 30211 | 3rd+ Episodes, 0 to 5 Therapy Visits | C2F1S1 | 0.4802 |
| 30212 | 3rd+ Episodes, 6 Therapy Visits | C2F1S2 | 0.6414 |
| 30213 | 3rd+ Episodes, 7 to 9 Therapy Visits | C2F1S3 | 0.8025 |
| 30214 | 3rd+ Episodes, 10 Therapy Visits | C2F1S4 | 0.9637 |
| 30215 | 3rd+ Episodes, 11 to 13 Therapy Visits | C2F1S5 | 1.1249 |
| 30221 | 3rd+ Episodes, 0 to 5 Therapy Visits | C2F2S1 | 0.5652 |
| 30222 | 3rd+ Episodes, 6 Therapy Visits | C2F2S2 | 0.7152 |
| 30223 | 3rd+ Episodes, 7 to 9 Therapy Visits | C2F2S3 | 0.8652 |
| 30224 | 3rd+ Episodes, 10 Therapy Visits | C2F2S4 | 1.0151 |
| 30225 | 3rd+ Episodes, 11 to 13 Therapy Visits | C2F2S5 | 1.1651 |
| 30231 | 3rd+ Episodes, 0 to 5 Therapy Visits | C2F3S1 | 0.6101 |
| 30232 | 3rd+ Episodes, 6 Therapy Visits | C2F3S2 | 0.7605 |
| 30233 | 3rd+ Episodes, 7 to 9 Therapy Visits | C2F3S3 | 0.9109 |
| 30234 | 3rd+ Episodes, 10 Therapy Visits | C2F3S4 | 1.0612 |
| 30235 | 3rd+ Episodes, 11 to 13 Therapy Visits | C2F3S5 | 1.2116 |
| 30311 | 3rd+ Episodes, 0 to 5 Therapy Visits | C3F1S1 | 0.5936 |
| 30312 | 3rd+ Episodes, 6 Therapy Visits | C3F1S2 | 0.7739 |
| 30313 | 3rd+ Episodes, 7 to 9 Therapy Visits | C3F1S3 | 0.9542 |
| 30314 | 3rd+ Episodes, 10 Therapy Visits | C3F1S4 | 1.1345 |
| 30315 | 3rd+ Episodes, 11 to 13 Therapy Visits | C3F1S5 | 1.3148 |
| 30321 | 3rd+ Episodes, 0 to 5 Therapy Visits | C3F2S1 | 0.6786 |
| 30322 | 3rd+ Episodes, 6 Therapy Visits | C3F2S2 | 0.8477 |

TABLE 5—CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

| Pay group | Description | Clinical and functional levels (1 = Low; 2 = Medium; 3 = High) | CY 2018 weight |
|-------------|--|---|----------------|
| 30323 | 3rd+ Episodes, 7 to 9 Therapy Visits | C3F2S3 | 1.0168 |
| 30324 | 3rd+ Episodes, 10 Therapy Visits | C3F2S4 | 1.1859 |
| 30325 | 3rd+ Episodes, 11 to 13 Therapy Visits | C3F2S5 | 1.3550 |
| 30331 | 3rd+ Episodes, 0 to 5 Therapy Visits | C3F3S1 | 0.7235 |
| 30332 | 3rd+ Episodes, 6 Therapy Visits | C3F3S2 | 0.8930 |
| 30333 | 3rd+ Episodes, 7 to 9 Therapy Visits | C3F3S3 | 1.0625 |
| 30334 | 3rd+ Episodes, 10 Therapy Visits | C3F3S4 | 1.2320 |
| 30335 | 3rd+ Episodes, 11 to 13 Therapy Visits | C3F3S5 | 1.4015 |
| 40111 | All Episodes, 20+ Therapy Visits | C1F1S1 | 1.7070 |
| 40121 | All Episodes, 20+ Therapy Visits | C1F2S1 | 1.7438 |
| 40131 | All Episodes, 20+ Therapy Visits | C1F3S1 | 1.7888 |
| 40211 | All Episodes, 20+ Therapy Visits | C2F1S1 | 1.8124 |
| 40221 | All Episodes, 20+ Therapy Visits | C2F2S1 | 1.8492 |
| 40231 | All Episodes, 20+ Therapy Visits | C2F3S1 | 1.8942 |
| 40311 | All Episodes, 20+ Therapy Visits | C3F1S1 | 2.0540 |
| 40321 | All Episodes, 20+ Therapy Visits | C3F2S1 | 2.0908 |
| 40331 | All Episodes, 20+ Therapy Visits | C3F3S1 | 2.1359 |

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2018 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 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2016 utilization (claims) data to total payments when CY 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2016 utilization data. This produces a case-mix budget neutrality factor for CY 2018 of 1.0160.

The following is a summary of the comments and our responses to comments on the CY 2018 case-mix weights:

Comment: A few commenters stated that CMS did not provide sufficient transparency of the details and methods used to recalibrate the HH PPS case-mix weights in the proposed rule. In addition, commenters stated that CMS provided little justification for recalibrating the case-mix weights just 1 year following the recalibration of case-mix weights in CY 2017, 2 years since the recalibration in 2016, and 5 years since the recalibration for the CY 2012 HH PPS final rule. The commenters noted that they opposed the recalibration of the case weights for CY 2018, but supported the budget neutrality adjustment to account for the recalibrated case-mix weights if CMS finalizes the recalibration.

Response: As stated in the CY 2018 HH PPS proposed rule (82 FR 35282), the methodology used to recalibrate the weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions as noted in the CY 2015 HH PPS proposed and final rules (79 FR 38366 and 79 FR 66032, respectively). In the CY 2015 HH PPS final rule, we finalized annual recalibration and the methodology to be used for each year's recalibration (79 FR 66072). For more detail, we also encourage commenters to refer to the CY 2012 HH PPS proposed and final rules (76 FR 40988 and 76 FR 68526, respectively) and the November 1, 2011 "Revision of the Case-Mix Weights for the HH PPS Report" on our home page at: <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html> for additional information about the recalibration methodology.

We note that in comparing the final CY 2018 HH PPS case-mix weights (see Table 5) to the final CY 2015 HH PPS case-mix weights (79 FR 66062), the case-mix weights change very little, with most case-mix weights either increasing or decreasing by 1 to 2 percent with no case-mix weights increasing by more than 3 percent or decreasing by more than 3 percent. The aggregate decreases in the case-mix weights are offset by the case-mix budget neutrality factor, which is applied to the national, standardized 60-day episode payment rate. In other words, although the case-mix weights themselves may increase or decrease from year-to-year, we correspondingly offset any estimated increases or

decreases in total payments under the HH PPS, as a result of the case-mix recalibration, by applying a budget neutrality factor to the national, standardized 60-day episode payment rate. For CY 2018, the case-mix budget neutrality factor will be 1.0160 as described previously. The recalibration of the case-mix weights is not intended to increase or decrease overall HH PPS payments, but rather is used to update the relative differences in resource use amongst the 153 groups in the HH PPS case-mix system and maintain the level of aggregate payments before application of any other adjustments. We will continue to monitor the performance of any finalized case-mix model, and will make changes to it as necessary.

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 2 through 5. For this final rule, the CY 2018 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2016 claims data as of August 17, 2017. 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 2018 HH PPS proposed rule.

C. CY 2018 Home Health Payment Rate Update

1. CY 2018 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2018 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket was rebased and revised in CY 2013. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080 through 67090).

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

Prior to the enactment of the MACRA, which amended section 1895(b)(3)(B) of the Act, the home health update percentage for CY 2018 would have been based on the estimated home health market basket update of 2.5 percent (based on IHS Global Inc.’s third-quarter 2017 forecast with historical data through second-quarter 2017). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of MACRA, the estimated CY 2018 home health market basket update of 2.5 percent would have been reduced by a MFP adjustment as mandated by the Affordable Care Act (currently estimated to be 0.6 percentage point for CY 2018). In effect, the home health payment update percentage for CY 2018 would have been 1.9 percent. However, section 411(c) of the MACRA amended section 1895(b)(3)(B) of the

Act, such that, for home health payments for CY 2018, the market basket percentage increase is required to be 1 percent.

Section 1895(b)(3)(B) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2018, the home health payment update will be –1 percent (1 percent minus 2 percentage points).

2. CY 2018 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We proposed to continue this practice for CY 2018, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we proposed to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013, and before October 1, 2014 (FY 2014 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary’s place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2018 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic

circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico’s various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2018, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB’s new area delineations using a 1-year transition. The most recent bulletin (No. 15–01) concerning the revised delineations was published by the OMB on July 15, 2015.

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

3. CY 2018 Annual Payment Update

a. Background

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

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate will continue to be 78.535 percent and the non-labor-related share will continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2018 HH PPS rates use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and will be adjusted as described in section III.B.

of this final rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

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

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

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

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

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

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim

for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

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

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

b. CY 2018 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2018 national, standardized 60-day episode payment rate, we apply a wage index budget neutrality factor; a case-mix budget neutrality factor described in section III.B. of this final rule; a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014, as finalized in the CY 2016 HH PPS final rule (80 FR 68646); and the home health payment update percentage

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

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the CY 2018 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2017 wage index. By dividing the total payments for non-LUPA episodes using the CY 2018 wage index by the total payments for non-LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0004. We will apply the wage index budget neutrality factor of 1.0004 to the calculation of the CY 2018 national, standardized 60-day episode rate.

As discussed in section III.B. of the proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed to apply a case-mix weight budget neutrality factor to the CY 2018 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2018 case-mix weights are applied to CY 2016 utilization (claims) data to total payments when CY 2017 case-mix weights are applied to CY 2016 utilization data. The case-mix budget neutrality factor for CY 2018 is 1.0160 as described in section III.B of this final rule.

Next, we apply a reduction of 0.97 percent to the national, standardized 60-day payment rate for CY 2018 to account for nominal case-mix growth between CY 2012 and CY 2014. Lastly, we will update the payment rates by the CY 2018 home health payment update percentage of 1 percent as mandated by section 1895(b)(3)(B)(iii) of the Act. The CY 2018 national, standardized 60-day episode payment rate is calculated in Table 6.

TABLE 6—CY 2018 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

| CY 2017 national, standardized 60-day episode payment | Wage index budget neutrality factor | Case-mix weights budget neutrality factor | Nominal case-mix growth adjustment (1–0.0097) | CY 2018 HH payment update | CY 2018 national, standardized 60-day episode payment |
|---|-------------------------------------|---|---|---------------------------|---|
| \$2,989.97 | × 1.0004 | × 1.0160 | × 0.9903 | × 1.01 | \$3,039.64 |

The CY 2018 national, standardized 60-day episode payment rate for an HHA that does not submit the required

quality data is updated by the CY 2018 home health payment update of 1

percent minus 2 percentage points and is shown in Table 7.

TABLE 7—CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

| CY 2017 national, standardized 60-day episode payment | Wage index budget neutrality factor | Case-mix weights budget neutrality factor | Nominal case-mix growth adjustment (1–0.0097) | CY 2018 HH payment update | CY 2018 national, standardized 60-day episode payment |
|---|-------------------------------------|---|---|---------------------------|---|
| \$2,989.97 | × 1.0004 | × 1.0160 | × 0.9903 | × 0.99 | \$2,979.45 |

c. CY 2018 National Per-Visit Rates

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

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

To calculate the CY 2018 national per-visit rates, we started with the CY 2017 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-

visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2018 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2017 wage index. By dividing the total payments for LUPA episodes using the CY 2018 wage index by the total payments for LUPA episodes using the CY 2017 wage index, we obtained a wage index budget neutrality factor of 1.0010. We apply the wage index budget neutrality factor of 1.0010 in order to calculate the CY 2018 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights.

Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2018 home health payment update percentage of 1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2018 national per-visit rates are shown in Tables 8 and 9.

TABLE 8—CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

| HH Discipline | CY 2017 per-visit payment | Wage index budget neutrality factor | CY 2018 HH payment update | CY 2018 per-visit payment |
|---------------------------|---------------------------|-------------------------------------|---------------------------|---------------------------|
| Home Health Aide | \$64.23 | × 1.0010 | × 1.01 | \$64.94 |
| Medical Social Services | 227.36 | × 1.0010 | × 1.01 | 229.86 |
| Occupational Therapy | 156.11 | × 1.0010 | × 1.01 | 157.83 |
| Physical Therapy | 155.05 | × 1.0010 | × 1.01 | 156.76 |
| Skilled Nursing | 141.84 | × 1.0010 | × 1.01 | 143.40 |
| Speech-Language Pathology | 168.52 | × 1.0010 | × 1.01 | 170.38 |

The CY 2018 per-visit payment rates for HHAs that do not submit the

required quality data are updated by the CY 2018 HH payment update percentage

of 1 percent minus 2 percentage points and are shown in Table 9.

TABLE 9—CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

| HH Discipline | CY 2017 per-visit rates | Wage index budget neutrality factor | CY 2018 HH payment update minus 2 percentage points | CY 2018 per-visit rates |
|---------------------------|-------------------------|-------------------------------------|---|-------------------------|
| Home Health Aide | \$64.23 | × 1.0010 | × 0.99 | \$63.65 |
| Medical Social Services | 227.36 | × 1.0010 | × 0.99 | 225.31 |
| Occupational Therapy | 156.11 | × 1.0010 | × 0.99 | 154.70 |
| Physical Therapy | 155.05 | × 1.0010 | × 0.99 | 153.65 |
| Skilled Nursing | 141.84 | × 1.0010 | × 0.99 | 140.56 |
| Speech-Language Pathology | 168.52 | × 1.0010 | × 0.99 | 167.00 |

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

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, in the case of HHAs that do submit the required quality data, for LUPA episodes that occur as the only episode or an initial

episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be \$264.59 (1.8451 multiplied by \$143.40), subject to area wage adjustment.

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

All medical supplies (routine and nonroutine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-routine include dressings for wound care, I.V. supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2018 NRS conversion factor, we updated the CY 2017 NRS conversion factor (\$52.50) by the CY 2018 home health payment update percentage of 1

percent. We did not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2018 is shown in Table 10.

TABLE 10—CY 2018 NRS CONVERSION FACTOR FOR HHAs THAT DO SUBMIT THE REQUIRED QUALITY DATA

| CY 2017 NRS conversion factor | CY 2018 HH payment update | CY 2018 NRS conversion factor |
|-------------------------------|---------------------------|-------------------------------|
| \$52.50 | × 1.01 | \$53.03 |

Using the CY 2018 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 11.

TABLE 11—CY 2018 NRS PAYMENT AMOUNTS FOR HHAs THAT DO SUBMIT THE REQUIRED QUALITY DATA

| Severity level | Points (scoring) | Relative weight | CY 2018 NRS payment amounts |
|----------------|------------------|-----------------|-----------------------------|
| 1 | 0 | 0.2698 | \$14.31 |
| 2 | 1 to 14 | 0.9742 | 51.66 |
| 3 | 15 to 27 | 2.6712 | 141.65 |
| 4 | 28 to 48 | 3.9686 | 210.45 |
| 5 | 49 to 98 | 6.1198 | 324.53 |
| 6 | 99+ | 10.5254 | 558.16 |

For HHAs that do not submit the required quality data, we updated the CY 2017 NRS conversion factor (\$52.50) by the CY 2018 home health payment update percentage of 1 percent minus 2 percentage points. The CY 2018 NRS conversion factor for HHAs that do not submit quality data is shown in Table 12.

TABLE 12—CY 2018 NRS CONVERSION FACTOR FOR HHAs THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

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

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 13.

TABLE 13—CY 2018 NRS PAYMENT AMOUNTS FOR HHAs THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

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

f. Rural Add-On

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

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

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

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

The following is a summary of the public comments received on the “CY 2018 Home Health Payment Rate Update” proposals and our responses:

Comment: Several commenters stated that they wanted CMS to rescind the nominal case-mix reduction for 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 may have eliminated any practice of assigning an inaccurate code to increase reimbursement and questioned the interaction between the rebasing adjustments, nominal case-mix growth reductions, and case-mix recalibration. A few commenters stated that the

baseline used in calculating the amount of case-mix growth was inappropriate. 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. 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.

Response: We finalized the nominal case-mix reduction for CY 2018 in the CY 2016 HH PPS final rule. We did not propose changes to the finalized reduction for CY 2018, nor did we propose any changes in the methodology used to calculate nominal case-mix growth in the CY 2018 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 through 68646), which include responses on the interaction between the rebasing and recalibration of the case-mix weights on the measurement of nominal case-mix growth between 2012 and 2014, our rationale for the methodology used to determine “real” versus “nominal” case-mix growth in CYs 2012–2014, the role of CBO estimates in our determination of nominal case-mix reductions, and our ability to target nominal case-mix reductions to certain providers rather than the industry as a whole. 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.

Comment: MedPAC stated that they have long believed that it was 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 their belief that the CY 2018 payment update of 1 percent is inadequate.

Response: We appreciate the commenters’ concerns. However, the 1 percent payment update for CY 2018 is mandated by section 1895(b)(3)(B)(iii) of the Act, as amended by section 411(c) of the MACRA.

Comment: Several commenters urged CMS to continue providing rural add-on payments in order that beneficiaries in rural communities continue to have access to home health services.

Response: The sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to re-authorize rural add-on payments for episodes and visits ending on or after January 1, 2018.¹¹ However, we plan to continue to monitor the costs associated with providing home health care in rural versus urban areas. We note that in Chapter 9 of its 2013 Report to Congress (available at http://medpac.gov/docs/default-source/reports/mar13_ch09.pdf?sfvrsn=0), MedPAC stated that the use of the “broadly targeted add-on, providing the same payment for all rural areas regardless of access, results in rural areas with the highest utilization drawing a disproportionate share of the add-on payments.” MedPAC stated that “70 percent of the episodes that received the add-on payments in 2011 were in rural counties with utilization significantly higher than the national average” and recommended that Medicare target payment adjustments for rural areas to those areas that have access challenges.

Comment: A commenter recommended that CMS explore policies that provide Medicare coverage for services from therapy providers who furnish telehealth services to their patients as proper application of telehealth rehabilitation therapy services, particularly in underserved areas, can potentially have a dramatic impact on improving care, diminishing negative consequences, and reducing costs.

Response: The definition of a visit for purposes of Medicare home health services as set forth in § 409.48(c) specifies that a visit is an episode of personal contact with the beneficiary by

¹¹ See U.S. CONST. art. I, § 9 (“No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law”).

staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service. A telephone contact or telehealth visit does not meet the definition of a visit and therefore does not count as a visit. While there is nothing to preclude an HHA from furnishing services via telehealth or other technologies that they believe promote efficiencies, those technologies are not specifically recognized and paid by Medicare under the home health benefit.

Comment: Several commenters expressed concerns with the wage index for rural areas in Maine, citing it as one of the lowest in New England. Another commenter questioned the validity of the wage index data, especially in the case of the CBSA for Albany-Schenectady-Troy, noting that in the past 5 years, this CBSA has seen its wage index reduced 5.41 percent, going from 0.8647 in 2013 to a proposed CY 2018 wage index of 0.8179.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The 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 Hospital Inpatient Prospective Payment System (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 IPPS rule each year, with the most recent discussion provided in the FY 2018 IPPS final rule (82 FR 38130 through 38136 and 82 FR 38152 through 38156). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter stated that CMS's decision to switch from MSAs to the CBSAs for the wage index calculation has had serious financial ramifications for New York HHAs. The commenter stated that CMS's shift to the CBSA wage index designation has resulted in below trend reimbursement for New York City agencies.

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.

Comment: Several commenters opposed the fact that hospitals are given the opportunity to appeal their annual wage index and apply for geographic reclassification while HHAs in the same geographic location are not given that same privilege. The commenters believe that this lack of parity between different health care sectors further exemplifies the inadequacy of CMS's decision to continue to use the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates. Another commenter suggests that CMS include wage data from reclassified hospitals in calculating rural wage index values.

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.

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 requested that CMS explore wholesale revision and reform of the home health wage index, including the development of a home health-specific wage index. Commenters noted that reform of the home health wage index should address the commenters' following concerns and opinions: (1) The impact on care access and financial stability of HHAs at the local level; (2) the unpredictable year-to-year swings in wage index values that are often based on inaccurate or incomplete hospital cost reports which have negatively impacted HHAs throughout the years and jeopardized access to care; (3) the inadequacy and inaccuracy of the pre-floor, pre-reclassified hospital wage index for adjusting home health costs; and (4) the labor market distortions created by reclassification of hospitals in areas in which home health labor costs are not reclassified.

Response: We appreciate the commenter's recommendation to continue exploring potential approaches for wage index reform, including collecting home health-specific wage data in order to establish a home health-specific wage index. We note that our previous attempts at either proposing or developing a home health-specific wage index were not well-received by the home health industry. In September 30, 1988 **Federal Register** notice (53 FR 38476), the Health Care Financing Administration (HCFA), as CMS was then known, implemented an HHA-specific wage index based on data received from HHAs. Subsequently, providers gave significant feedback concerning the burden that the reporting requirements posed and the accuracy of the data. As a result, the Medicare Catastrophic Coverage Act of 1988 retroactively repealed the use of an HHA-specific wage index and referenced use of the hospital wage index (see section 1895(b)(4)(C) of the Act). While this occurred many years ago, we believe that HHAs would voice similar concerns regarding the burden such reporting requirements would place on HHAs.

Consistent with our previous responses to these recurring comments (most recently published in the CY 2016 HH PPS final rule (80 FR 68654)), we also note that developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the HHA cost report data in order for it to be used as part of this analysis. This audit process is quite extensive in the case of approximately

3,300 hospitals, it would be significantly more so in the case of approximately 11,000 HHAs. We believe auditing all HHA cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would also place a burden on providers in terms of recordkeeping and completion of the cost report worksheet.

We also believe that adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are more than three times as many HHAs as there are hospitals. Therefore, we continue to believe that, in the absence of the appropriate home health-specific wage data, using the pre-floor, pre-reclassified inpatient hospital wage data is appropriate and reasonable for the HH PPS.

Finally, CMS has conducted research on a possible alternative to the hospital wage index. CMS issued its "Report to Congress: Plan to Reform the Medicare Wage Index" concerning the hospital wage index, on April 11, 2012 and is available on our Wage Index Reform Web page <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html>. This report describes the concept of a commuting-based wage index (CBWI). However, 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. In considering alternative methodologies for area wage adjustment, CMS would have to consider whether the benefits of such methodologies outweigh the reporting, record keeping and audit burden that would be placed on HHAs and/or other providers.

Comment: Several commenters stated that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting home health costs, particularly in states like New York, which has among the nation's highest labor costs, exacerbated, in the commenters' opinions, by their state's implementation of a phased-in \$15 per-hour minimum wage hike, which they argue would be unfunded by Medicare. The commenters estimated that the minimum wage mandate, when fully phased-in, would add \$2 billion in costs for that state's HHAs across all payers (Medicaid, Medicare, managed care, commercial insurance and private-pay), and would not be captured by the pre-floor, pre-reclassified hospital wage

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

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

Comment: Commenters raised issues with CMS's decision to maintain the current policy of using the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates because this resulted in volatility in the home health wage index from one year to the next. These commenters believe that what they view as unpredictable year-to-year swings in wage index values were based on inaccurate or incomplete hospital cost reports.

Response: We appreciate the commenters' concerns regarding the accuracy of the home health wage index. 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, including a wage data verification and correction process, are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2018 IPPS final rule (82 FR 38130 through 38136, and 82 FR 38152 through 38156). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter recommended that CMS research the impact of instituting a population density adjustment to the labor portion of the HH PPS payments.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually 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 home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas.

Final Decision: After considering the comments received in response to the CY 2018 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 2018, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2013 and before October 1, 2014 (FY 2014 cost report data). In addition, we are implementing the third and final year of a 0.97 percent payment reduction to account for nominal case-mix growth from CY 2012 through CY 2014 when finalizing the CY 2018 HH PPS payment rates. We note that 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 2018 proposed rule.

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

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. 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. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 3, 2000 Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes

whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS proposed rule (74 FR 40948, 40957), we stated that outlier payments increased as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007 and that this excessive growth in outlier payments was primarily the result of unusually high outlier payments in a few areas of the country. In that discussion, we noted that despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent target in CY 2007 and, in the absence of corrective measures, would continue to do so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. As described in the CY 2010 HH PPS final rule (74 FR 58080 through 58087), to mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we finalized an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total home health expenditures). For CY 2010, we first returned the 5 percent held for the previous target outlier pool to the national, standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399),

section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes may not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

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

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76724), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76724), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into

per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule (81 FR 76725) we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes. Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

2. Fixed Dollar Loss (FDL) Ratio

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

Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

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

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

to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

Using preliminary CY 2016 claims data (as of March 17, 2017) and the proposed CY 2018 payment rates presented in section III.C. of the CY 2018 HH PPS proposed rule (82 FR 35293), we estimated that outlier payments would constitute approximately 2.47 percent of total HH PPS payments in CY 2018 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we did not propose a change to the FDL ratio for CY 2018 as we believed that maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 was still appropriate given the percentage of outlier payments projected for CY 2018.

Likewise, we did not propose a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, Inpatient Rehabilitation Facility (IRF) PPS, IPPS, etc.). While we did not propose to change the FDL ratio of 0.55 for CY 2018, we noted that we would update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2016 claims data as of June 30, 2017 or later) in this final rule.

Using updated CY 2016 claims data (as of August 18, 2017) and the final CY 2018 payment rates presented in section III.C of this final rule, we estimate that outlier payments would continue to constitute approximately 2.47 percent of total HH PPS payments in CY 2018 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we continue to believe that maintaining an

FDL ratio of 0.55 with a loss-sharing ratio of 0.80 is still appropriate given the percentage of outlier payments projected for CY 2018.

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

Comment: A commenter questioned if we would provide the CY 2018 cost-per-unit values to be used for the outlier calculation.

Response: The cost-per-unit amounts for CY 2018 are in Table 14 of this final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727).

TABLE 14—CY 2018 COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS *

| Visit type | CY 2018 National per-visit payment rates | Average minutes-per-visit | Cost-per-unit (1 unit = 15 minutes) |
|---------------------------------|--|---------------------------|-------------------------------------|
| Home health aide | \$64.94 | 63.0 | \$15.46 |
| Medical social services | 229.86 | 56.5 | 61.02 |
| Occupational therapy | 157.83 | 47.1 | 50.26 |
| Physical therapy | 156.76 | 46.6 | 50.46 |
| Skilled nursing | 143.40 | 44.8 | 48.01 |
| Speech-language pathology | 170.38 | 48.1 | 53.13 |

* These values reflect the national per visit rates for each discipline for providers who have submitted quality data; for rates applicable to those providers who did not submit quality data submitted, please see our forthcoming CY 2018 Rate Update Change Request, which will be available here: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-Transmittals.html>.

We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

Comment: Several commenters stated that the changes to the outlier methodology made in the CY 2017 final rule, particularly the increase in the FDL ratio from 0.45 to 0.55, were significant and may have led to a reduction in the number of home health episodes that would qualify for outlier payment. The commenters recommended that CMS release data on the impact of this policy change on the dually eligible beneficiary population and in particular those patients with clinically complex conditions.

Response: We appreciate the commenters' concerns regarding the potential impact of the changes to the outlier policy finalized in the CY 2017 HH PPS final rule (81 FR 76727). Data

reflecting the changes to the outlier policy made for CY 2017 are not yet available for analysis and assessment. However, as these updated data become available, we will evaluate for changes, analyze patterns in home health outlier payments, and monitor for any impacts, particularly for those beneficiaries with clinically complex conditions, and may include the results of such efforts in future rulemaking.

Additionally, as discussed in the CY 2017 HH PPS final rule (81 FR 76728), the goal of this policy change is to more accurately pay for outlier episodes. We noted in the CY 2017 HH PPS proposed rule that analysis indicates that a larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments (81 FR 43713). The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care.

In section II.D. of the CY 2018 HH PPS proposed rule (82 FR 35275), we discussed Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses. We believe that this change in the outlier payment policy may ultimately serve to 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.

Moreover, the 2.5 percent target of outlier payments to total home health payments is a statutory requirement, as established in section 1895(b)(5) of the Act. Therefore, we modified the FDL in order to align the estimated outlier payments with the 2.5 percent target required by law.

Comment: A few commenters expressed disagreement with CMS's decision to maintain the existing 10-percent cap on outlier payments to HHAs as a purported fraud-fighting effort, suggesting that a potentially more appropriate and targeted fraud-fighting initiative will include a possible minimum provider-specific number or percent of episodes that result in LUPAs, suggesting that reporting periods with zero LUPAs could be an indicator of inappropriate provider behavior.

Response: Regarding the appropriateness of the 10 percent per-agency cap, we note that the 2.5 percent target of outlier payments to total home health payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as established in section 1895(b)(5) of the Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent target amount. Additionally, we appreciate the commenter's suggestion regarding alternative approaches for targeting fraud within the Medicare home health benefit. The Program for Evaluating Payment Patterns Electronic Report (PEPPER) is a comparative data report that summarizes a single provider's Medicare claims data statistics for services vulnerable to improper payments. PEPPER can support a hospital or facility's compliance efforts by identifying where its billing patterns are different from the majority of other providers in the nation. This data can help identify both potential overpayments and potential underpayments, and can provide guidance on areas in which a provider may want to focus auditing and monitoring efforts with the goal of preventing improper Medicare payments. In the HHA PEPPER, we include a metric for non-LUPA payment, which represents the count of episodes paid to the HHA that did not have a LUPA payment during the report period as a proportion of total episodes paid to the HHA during the report period (available at: https://www.pepperresources.org/Portals/0/Documents/PEPPER/HHA/HHA_PEPPERUsersGuide_Edition2.pdf). This measure is provided to the HHA community for review and may also be used by our Center for Program Integrity as a guide for audits and other investigative efforts.

We also note that, as described in the CY 2017 HH PPS final rule (82 FR 76727), 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 significantly impact a large portion of HHAs.

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

Response: As established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10-percent cap on outlier payments at the home health agency level are statutory requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5-percent target amount. However, we will continue to evaluate for the appropriateness of those elements of the outlier policy that may be modified, including the FDL and the loss-sharing ratio. We note that other Medicare payment systems with outlier payments, such as the IRF PPS and IPPS, annually reassess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

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

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

Final Decision: We are finalizing no change to the FDL ratio or loss sharing ratio for CY 2018. We are maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 for CY 2018. However, we will continue to monitor outlier payments and continue to explore ways to maintain an outlier policy for

episodes that incur unusually high costs.

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

We proposed case-mix methodology refinements through the implementation of the Home Health Groupings Model (HHGM). We proposed to implement the HHGM for home health periods of care beginning on or after January 1, 2019. The HHGM uses 30-day periods rather than the 60-day episode used in the current payment system, eliminates the use of the number of therapy visits provided to determine payment, and relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories.

We are not finalizing the implementation of the HHGM in this final rule. We received many comments from the public that we would like to take into further consideration. While commenters were generally supportive of the concept of revising the HH PPS case-mix methodology to better align payments with the costs of providing care, commenters included technical comments on various aspects of the proposed case-mix adjustment methodology under the HHGM and were most concerned about the proposed change in the unit of payment from 60 days to 30 days and such change being proposed for implementation in a non-budget neutral manner. Commenters also stated their desire for greater involvement in the development of the HHGM and the need for access to the necessary data in order to replicate and model the effects on their businesses.

We note that information continues to be available to stakeholders around this important initiative. The analyses and the ultimate development of HHGM was previously shared with both internal and external stakeholders via technical expert panels, clinical workgroups, and special open door forums. We provided high-level summaries on our case-mix methodology refinement work in the HH PPS proposed rules for CYs 2016 and 2017 (80 FR 39839, and 81 FR 76702). Additionally, a detailed technical report was posted on the CMS Web site in December 2016 and remains available, additional technical expert panel and clinical workgroup webinars were held after the posting of the technical report, and a National Provider call occurred in January 2017 to further solicit feedback from stakeholders and the general

public.¹² As many did, any provider or organization wishing to receive the necessary data to replicate and model the effects of the HHGM or study the Medicare home health benefit can submit a request through the CMS Data Request Center.¹³ We note that the Home Health Agency Limited Data Set files and Research Identifiable Files are available on a quarterly and annual basis. The fourth quarter data for CY 2016 were available in mid-May of 2017. The fourth quarter files include all final action fee-for-service claims received by December 31, 2016. We also posted a HHGM Groupings Tool along with the CY 2018 HH PPS proposed rule on the HHA Center Web page, which providers can continue to use in order to replicate the HHGM methodology using their own internal data.

We also note that, in the CY 2018 HH PPS proposed rule, we assumed that behavioral responses would occur upon implementation of the HHGM. If no behavioral assumptions were made and we implemented the HHGM for CY 2018, we estimate that the 30-day payment amount needed to achieve budget neutrality would have been \$1,722.29. However, because we have a continued fiduciary duty as stewards of the Medicare program to mitigate potential overpayments, if possible, we assumed behavioral responses would occur in the estimation of the 30-day payment amount. We determined that, if the HHGM were implemented for CY 2018 with assumed behavioral responses, the 30-day payment amount needed to achieve budget neutrality would have been \$1,622.61. For the CY 2018 HH PPS proposed rule, we included two behavioral assumptions in our impact estimates related to the proposed implementation of the HHGM for CY 2019: (1) For LUPAs one visit under the proposed HHGM case-mix group thresholds, HHAs would provide an additional visit so the 30-day period of care becomes a non-LUPA; and (2) the highest-paying diagnosis code would be listed as primary for clinical grouping assignment. While we do not support or condone coding practices or the provision of services solely to maximize payment, we often take into account expected behavioral effects of policy changes related to rate setting. We included a LUPA behavioral assumption in our estimated impact of the HHGM based on past behavioral assumptions made under the HH PPS.

As noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, about 7 percent of all 60-day episodes receive a LUPA. For the HHGM, approximately 7 percent of 30-day periods would receive a LUPA. However, because 4.9 percent of 30-day periods of care are just one visit below the LUPA thresholds under the HHGM, we assume that for these 30-day periods, HHAs will provide an additional visit to avoid receiving a LUPA, especially in the absence of the therapy thresholds and the change from a 60-day to 30-day unit of payment.

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption was based on decades of past experience under the HH PPS and other case-mix systems, such as the implementation of the diagnosis-related groups (DRGs) and the Medicare Severity (MS)-DRGs under the inpatient prospective payment system. In the FY 2008 IPPS final rule (72 FR 47176), we noted that case-mix refinements can lead to substantial unwarranted increase in payments. To address this issue when CMS transitioned from DRGs to MS-DRGs, MedPAC recommended that the Secretary project the likely effect of reporting improvements on total payments and make an offsetting adjustment to the national average base payment amounts (72 FR 47176). In the FY 2008 IPPS final rule (72 FR 47181), we summarized instances where case-mix increases resulted from documentation and coding-induced changes for the first year of the IRF PPS and in Maryland hospitals' transition to APR DRGs (estimated at around 5 percent in both instances). Therefore, we estimated that an adjustment of 4.8 percent would be necessary to maintain budget neutrality for the transition to the MS-DRGs (72 FR 47178). With regards to experience under the HH PPS, as outlined in the CY 2018 HH PPS proposed rule (82 FR 35274), between CY 2000 and 2010, total case-mix change was 23.90 percent, with 20.08 considered nominal case-mix growth, an average of approximately 2 percent nominal case-mix growth per year.

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

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1,

2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified HHAs providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs providing services in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model will utilize the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on: (1) A set of measures already reported via OASIS and HHCAPPS for all patients serviced by the HHA and select claims data elements; and (2) three new measures where points are achieved for reporting data.

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

¹² <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html>.

¹³ <https://www.resdac.org/cms-data/request/cms-data-request-center>.

- Calculating benchmarks and achievement thresholds at the state level rather than the level of the size-cohort and revising the definition for benchmark to state that benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state.

- Requiring a minimum of eight HHAs in a size-cohort.
- Increasing the timeframe for submitting new measure data from seven calendar days to 15 calendar days following the end of each reporting period to account for weekends and holidays.
- Removing four measures (Care Management: Types and Sources of Assistance, Prior Functioning Activities of Daily Living (ADL)/Instrumental ADL (IADL), Influenza Vaccine Data Collection Period, and Reason Pneumococcal Vaccine Not Received) from the set of applicable measures.
- Adjusting the reporting period and submission date for the Influenza Vaccination Coverage for Home Health Personnel measure from a quarterly submission to an annual submission.
- Allowing for an appeals process that includes the recalculation process finalized in the CY 2016 HH PPS final rule (80 FR 68688 through 68689), as modified, and adds a reconsideration process.

B. Quality Measures

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

The HHCAPHS survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1) Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between HHAs on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.

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

However, as we stated in the CY 2018 HH PPS proposed rule (82 FR 35333), we believe that using a minimum of 40 completed HHCAPHS surveys, rather than a minimum of 20 completed HHCAPHS surveys, will better align the Model with HHCAPHS policy for the Patient Survey Star Ratings on Home Health Compare (82 FR 35333).¹⁴ The decision to use a minimum of 40 completed surveys for these star ratings was a result of balancing two competing goals. One goal was to provide star ratings that were meaningful and minimized random variations. This goal was best served by calculating star ratings for large numbers of cases by having a larger minimum of completed HHCAPHS surveys (for example, 50 or 100 completed HHCAPHS surveys). At the same time, we also wanted to be able to provide star ratings for as many HHAs as possible. This goal was best served by using a lower minimum of completed HHCAPHS surveys (for example, 20 completed HHCAPHS surveys). We chose to balance these opposing and necessary goals by using 40 completed HHCAPHS surveys for the Patient Survey Star Ratings. Because we believe that aligning the Patient Survey Star Ratings system and the HHVBP Model provides uniformity, consistency, and standard transformability for different healthcare platforms, we proposed using a minimum of 40 instead of 20 completed HHCAPHS surveys under the HHVBP Model (82 FR 35333).

In the CY 2018 HH PPS proposed rule (82 FR 35333), we noted that we received a comment in response to the CY 2016 HH PPS proposed rule in support of using a higher minimum

threshold for HHCAPHS completed surveys for the Patient Survey Star Ratings if the data are going to be used in HHVBP or any other quality assessment program. We also noted that we received public comment in response to the CY 2017 HH PPS proposed rule in support of using a higher minimum threshold for HHCAPHS completed surveys in the HHVBP Model, including a recommendation to use a minimum of 100 HHCAPHS rather than a sample size of 20 surveys (82 FR 35333). We stated in the CY 2018 HH PPS proposed rule (82 FR 35333) that we believe that proposing a minimum of 40 completed HHCAPHS surveys for the Model would be more appropriate than the higher minimums previously recommended by some commenters because it represents a balance between providing meaningful data and having sufficient numbers of HHAs with performance scores for at least 5 measures in the cohorts. Moreover, using a minimum of 40 completed HHCAPHS surveys aligns with the Patient Survey Star Ratings on Home Health Compare (82 FR 35333).

To understand the possible impact of our proposal to use a minimum of 40 HHCAPHS completed surveys, we noted in the CY 2018 HH PPS proposed rule (82 FR 35333) that HHAs may refer to the Interim Performance Reports (IPRs) issued in October 2016, January 2017 and April 2017, which analyzed 40 or more completed HHCAPHS surveys to determine each HHA's HHCAPHS quality measure scores. As a point of comparison to the minimum of 40 HHCAPHS completed surveys, these IPRs were reissued using a minimum of 20 or more completed HHCAPHS surveys and included quality measure scores, for these same time periods, calculated with HHAs that qualify for the LEF by having sufficient data for at least five measures. HHAs had the opportunity to submit a request for recalculation of the revised interim performance scores.

HHAs had an opportunity to evaluate these IPRs in light of the proposal to change to a minimum of 40 HHCAPHS completed surveys, as well as seek clarification on the difference in their reports. The participating HHAs received concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports, which we made available in August 2017. The concurrent reports showed one report with HHCAPHS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAPHS quality measure scores calculated based on a minimum of 20

¹⁴ Patient Survey Star Ratings <https://www.medicare.gov/HomeHealthCompare/Data/Patient-Survey-Star-Ratings.html>.

completed surveys. Because the CY 2018 HH PPS proposed rule would not be finalized before the timeline for submission of recalculation and reconsideration requests, we noted HHAs would have the opportunity to submit recalculation requests for the interim performance scores based on both a minimum of 40 and 20 completed surveys, and recalculation and reconsideration requests, as applicable, for the annual total performance scores included in these reports for these thresholds in accordance with the appeals process set forth at § 484.335, which was finalized in the CY 2017 HH PPS final rule (82 FR 35333).

As discussed in the CY 2018 HH PPS proposed rule (82 FR 35333 through 35334), we analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAPHS surveys as compared to using 20 or more completed HHCAPHS surveys by examining OASIS measures submitted from January 1, 2015 through December 31, 2016, claims measures submitted from September 1, 2015 through September 30, 2016, and 12 months ending June 30, 2016 for HHCAPHS-based measures. We found that achievement thresholds, which are calculated as the median of all HHAs' performance on the specified quality measures during the 2015 baseline year for each state, would not change by more than ± 1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAPHS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (-1.1 percent). Benchmarks (the mean of the top decile of Medicare-certified HHA performance on the specified quality measures during the 2015 baseline year, calculated for each state) had greater potential for change, ranging down to -3.2 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a -2.0 percent change in the benchmark for the HHCAPHS *Willingness to Recommend the Agency* measure for Arizona and a -1.7 percent change in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a -1.7 percent change in the benchmark for the HHCAPHS *Communications between Providers and Patients* measure for Arizona, a -1.7 percent change in the benchmark for Florida, and a -3.2 percent change in the benchmark for Nebraska. Overall, the proposed change

in the HHCAPHS minimum of 40 completed surveys was estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from -0.4 through +2.2 percent. We provided estimates of the expected payment adjustment distribution based on the proposed minimum of 40 completed HHCAPHS surveys in the impact analysis of the CY 2018 HH PPS proposed rule (82 FR 35387)."

We invited public comment on our proposal to use 40 or more completed HHCAPHS surveys as the minimum to generate a quality measure score on the HHCAPHS measures, as is currently used in Home Health Compare and the Patient Survey Star Ratings. Therefore, we proposed to revise the definition of "applicable measure" at § 484.305 from a measure for which the competing HHA has provided 20 home health episodes of care per year to a measure for which a competing HHA has provided a minimum of 20 home health episodes of care per year for the OASIS-based measures, 20 home health episodes of care per year for the claims-based measures, or 40 completed surveys for the HHCAPHS measures. We proposed that if finalized, this policy would apply to the calculation of the benchmark and achievement thresholds and the calculation of performance scores for all Model years, beginning with PY 1.

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

Comment: Most commenters supported CMS' proposal to adjust the minimum number of completed Home Health Care Consumer Assessment of Healthcare Providers and System (HHCAPHS) Surveys. Several of these commenters expressed that it will result in more reliable and valid data results, as well as better align with the Patient Survey Star Ratings policy. A few commenters expressed concern about the proposed change and that using a minimum of 40 completed HHCAPHS surveys will greatly reduce the number of agencies with data sufficient for Model participation. A commenter specifically requested that CMS provide a clear and separate announcement regarding the change in survey minimum, how to interpret changes in total performance scores, and how to engage in the appeals process. Finally, a few commenters were concerned that smaller volume agencies will be negatively impacted, or forced to close, given the shift from 20 to 40 completed HHCAPHS surveys.

Response: We appreciate commenters' support for our proposal to use a

minimum of 40 completed HHCAPHS surveys, rather than a minimum of 20 completed HHCAPHS surveys. We continue to believe that a minimum of 40 completed HHCAPHS surveys, rather than a minimum of 20 completed HHCAPHS surveys, better aligns the Model with HHCAPHS policy for the Patient Survey Star Ratings on Home Health Compare. As discussed in the proposed rule, we believe that aligning the Patient Survey Star Ratings and the HHVBP Model will provide uniformity, consistency, and standard transformability for different healthcare platforms. While we recognize that this change could result in fewer agencies receiving a measure score on the HHCAPHS measures, we believe, as indicated in the proposed rule, that using a minimum of 40 completed HHCAPHS surveys represents an appropriate balance between providing meaningful data and having sufficient numbers of HHAs with performance scores on five other measures (for example OASIS based and claims based) to be included in the LEF. As we discuss later in this section, however, our updated analysis using full CY 2016 data found that no HHA fell below the minimum of having five measures to generate a TPS as a result of using a minimum of 40 rather than 20 completed HHCAPHS surveys.

For purposes of this final rule, we analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAPHS surveys as compared to using 20 or more completed HHCAPHS surveys by examining OASIS, claims and HHCAPHS measures from January 1, 2016 to December 31, 2016. We found that achievement thresholds will not change by more than ± 1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAPHS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (-1.1 percent). Benchmarks continued to have greater potential for change, ranging down to -3.1 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a -2.0 percent change in the benchmark for the HHCAPHS *Willingness to Recommend the Agency* measure for Arizona and a -1.7 percent change in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a -1.6 percent change in the benchmark for the HHCAPHS *Communications between Providers and*

Patients measure for Arizona, a -1.7 percent change in the benchmark for Florida, and a -3.1 percent change in the benchmark for Nebraska.

Overall, based on this updated analysis using full CY 2016 data, the proposed change in the HHCAHPS minimum of 40 completed surveys was estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from -0.3 percent through $+1.8$ percent and the majority of the states were close to zero. Additionally, the updated analysis using full CY 2016 data found that there were no Medicare-certified HHAs in the selected states that fell below the minimum of having five measures to generate a TPS for CY 2018 as a result of using a minimum of 40 rather than 20 completed HHCAHPS surveys.

To provide HHAs with information on the effects of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, we reissued the October 2016, January 2017 and April 2017 IPRs, which analyzed 40 or more completed HHCAHPS surveys, so that they could be recalculated with HHAs that have 20 or more completed HHCAHPS surveys. Moreover, CMS provided HHAs with concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports in August 2017 to show one report with HHCAHPS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAHPS quality measure scores calculated based on a minimum of 20 completed surveys. HHAs also had the opportunity to submit recalculation requests for the interim performance scores and recalculation and reconsideration requests, as applicable, for the annual total performance scores, in accordance with the process set forth at § 484.335. Additionally, we provided a number of webinars and other information on the interpretation of the quality measure scores and the Total Performance Scores and on the appeals process. More specifically, we provided all HHAs with a questions and answers document on the use of HHCAHPS measures in HHVBP Model performance reports when the reissued and concurrent IPRs were made available. These reports and communications provided points of comparison, clarification and information on the potential impact of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, to generate a quality measure score on the HHCAHPS measures. CMS notes that no recalculation requests on

the reissued and concurrent IPRs were received and no recalculation or reconsideration requests on the concurrent Annual Reports were received that related to our proposal to change to the minimum of 40 completed HHCAHPS surveys.

The change from a minimum of 20 completed HHCAHPS surveys to a minimum of 40 completed HHCAHPS surveys was not intended to negatively impact smaller agencies. We do not believe smaller HHAs will be disadvantaged by this change to a minimum of 40, because given their exemption from HHCAHPS reporting requirements, it is unlikely they would be measured on HHCAHPS under the Model and they can still compete on other measures.

We will continue to monitor the impacts of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, for purposes of receiving a performance score for any of the HHCAHPS measures.

Comment: A commenter suggested that because one negative survey might affect a score based on a minimum of 20 completed HHCAHPS surveys, removing the lowest and highest HHCAHPS for HHAs may be an effective method to align with the average customer response.

Response: We believe this comment is outside of the scope of the proposed methodology change in the CY 2018 HH PPS proposed rule to use a minimum of 40 completed HHCAHPS surveys rather than a minimum of 20 completed HHCAHPS surveys. However, we note that we believe each HHCAHPS survey may be an important avenue for public quality reporting and continued improvement within the HHA environment.

Final Decision: For the reasons stated previously and in consideration of the comments received, we are finalizing our proposal to amend the definition of “applicable measure” to mean a measure for which a competing HHA has provided a minimum of 40 completed surveys for HHCAHPS measures, for purposes of receiving a performance score for any of the HHCAHPS measures, beginning with PY1. In addition, we are finalizing a few minor technical edits to the regulation at § 484.305 to replace the colon and spell out “twenty” and “forty” (rather than “20” and “40”).

2. Removal of One OASIS-Based Measure Beginning With Performance Year 3

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in

Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 new measures (80 FR 68671 through 68673) for the HHVBP Model to be used in PY 1, referred to as the starter set.

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the services HHAs provide; (2) Incorporate the flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) Develop ‘second generation’ (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) Include a balance of process, outcome and patient experience measures; (5) Advance the ability to measure cost and value; (6) Add measures for appropriateness or overuse; and (7) Promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains¹⁵ (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) care coordination; (3) population & community health; (4) person- and caregiver-centered experience and outcomes; (5) safety; and (6) efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule (80 FR 68671 through 68673) identified 15 outcome measures (five from the HHCAHPS, eight from Outcome and Assessment Information Set (OASIS), and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three new measures, which were not previously reported in the home health setting).

In the CY 2017 HH PPS final rule (81 FR 76743 through 76747), we removed the following four measures from the measure set for PY 1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule.

For PY 3, we proposed to remove one OASIS-based measure, Drug Education

¹⁵ 2015 Annual Report to Congress, <http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm>.

on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures (82 FR 35334). We stated in the CY 2018 HH PPS proposed rule that, as part of our ongoing monitoring efforts, we found that based on the standard metrics of measure performance, many providers have achieved full performance on the Drug Education measure. For example, for the January 2017 IPRs (which covered the 12-month period of October 1, 2015 through September 30, 2016), the average value for this measure across all participating HHAs was 95.69 percent from October 2015 through September 2016. When looking at September 2016, the mean value on this measure across all participating HHAs had increased to 97.8 percent. In addition, we noted that there are few HHAs with poor performance on the measure. Based on the January 2017 IPRs, across all participating HHAs, the 10th percentile was 89 percent and the 5th percentile was 81.8 percent, but only 1.8 percent of HHAs had a value below 70 percent on the measure. We stated in the CY 2018 HH PPS proposed rule (82 FR 35334) that we believe that removing this measure would be consistent with our policy, as noted in the CY 2017 HH PPS final rule (81 FR 76746), that when a measure has achieved full performance, we may propose the removal of the measure in future rulemaking. In addition, our contractor's Technical Expert Panel (TEP), which consists of 11 panelists with expertise in home health care and quality measures, expressed concern that the Drug Education measure does not capture whether the education provided by the HHA was meaningful.

We presented the revised set of applicable measures, reflecting our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, in Table 43 of the CY 2018 HH PPS proposed rule. We stated that this measure set would be applicable to PY3 and each subsequent performance year until such time that another set of

applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking (82 FR 35334 through 35336).

We invited public comment on the proposal to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent performance years and Table 43 of the CY 2018 HH PPS proposed rule. The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters expressed support for removing the OASIS-based quality measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures as it has "topped out."

Response: We appreciate the support regarding the proposed removal of the "Drug Education" measure from the HHVBP Model's set of applicable measures because it has "topped out". We are finalizing the removal of the "Drug Education" measure as most providers have achieved full performance on the measure.

Comment: Several commenters provided feedback regarding the measure set more generally and some were outside of the scope of the proposed change. A commenter recommended that CMS consider assigning 50 percent of the "Star Rating" and HHVBP performance to claims-based measures and Patient Satisfaction, as the commenter believed that these measures are difficult or impossible to manipulate, and then assign the other 50 percent to OASIS-based self-reported measures. A commenter expressed concern that the measure set for the HHVBP Model mainly requires improvement in patient functioning and that this conflicts directly with the *Jimmo v. Sebelius* settlement.¹⁶ Another commenter recommended replacing the *Pneumococcal Polysaccharide Vaccine Ever Received* (NQF#0525) because the measure no longer reflects current

recommendations of the Advisory Committee for Immunization Practice (ACIP).

Response: We appreciate the comments on the measures methodology and, as discussed in the CY 2016 HH PPS final rule (80 FR 68669) and CY 2017 HH PPS final rule (81 FR 76747), 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 provisions revised as part of *Jimmo v. Sebelius* settlement. As stated in those rules, 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. As discussed in prior years, we will continue to seek and consider input we have received on the measure set for the HHVBP Model.

Final Decision: We are finalizing our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent years, as reflected in Table 15. Table 15 identifies the applicable measures set for PY3 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

TABLE 15—MEASURE SET FOR THE HHVBP MODEL* BEGINNING PY 3

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

¹⁶ *Jimmo v. Sebelius* Settlement Agreement Fact Sheet: <https://www.cms.gov/Medicare/Medicare->

[https://www.cms.gov/Medicare/Medicare-
Fee-for-Service-Payment/SNFPSP/Downloads/
Jimmo-FactSheet.pdf.](https://www.cms.gov/Medicare/Medicare-)

TABLE 15—MEASURE SET FOR THE HHVBP MODEL * BEGINNING PY 3—Continued

| NQS domains | Measure title | Measure type | Identifier | Data source | Numerator | Denominator |
|--|--|---------------|---------------|----------------|---|--|
| Clinical Quality of Care. | Improvement in Bed Transferring. | Outcome | NQF0175 | OASIS (M1850). | Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care. | Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Clinical Quality of Care. | Improvement in Bathing. | Outcome | NQF0174 | OASIS (M1830). | Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care. | Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Clinical Quality of Care. | Improvement in Dyspnea. | Outcome | NA | OASIS (M1400). | Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care. | Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Communication & Care Coordination. | Discharged to Community. | Outcome | NA | OASIS (M2420). | Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge. | Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Efficiency & Cost Reduction. | Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health. | Outcome | NQF0171 | CCW (Claims) | Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay. | Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days. |
| Efficiency & Cost Reduction. | Emergency Department Use without Hospitalization. | Outcome | NQF0173 | CCW (Claims) | Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay. | Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days. |
| Patient Safety | Improvement in Pain Interfering with Activity. | Outcome | NQF0177 | OASIS (M1242). | Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care. | Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Patient Safety | Improvement in Management of Oral Medications. | Outcome | NQF0176 | OASIS (M2020). | Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care. | Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Population/Community Health. | Influenza Immunization Received for Current Flu Season. | Process | NQF0522 | OASIS (M1046). | Number of home health episodes during which patients (a) received vaccination from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have received vaccination from another provider. | Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Population/Community Health. | Pneumococcal Polysaccharide Vaccine Ever Received. | Process | NQF0525 | OASIS (M1051). | Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV). | Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions. |
| Patient & Caregiver-Centered Experience. | Care of Patients | Outcome | | CAHPS | NA | NA. |
| Patient & Caregiver-Centered Experience. | Communications between Providers and Patients. | Outcome | | CAHPS | NA | NA. |
| 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. |

TABLE 15—MEASURE SET FOR THE HHVBP MODEL * BEGINNING PY 3—Continued

| NQS domains | Measure title | Measure type | Identifier | Data source | Numerator | Denominator |
|---|---|---------------|--|--------------------------------------|---|--|
| Patient & Care-giver-Centered Experience. Population/Community Health. | Willingness to recommend the agency. | Outcome | | CAHPS | NA | NA. |
| | 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. |

* Notes: For more detailed information on the 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/Medicaid/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>. For information on HHCAHPS measures see <https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx>.

C. Quality Measures for Future Consideration

The CY 2016 HH PPS final rule discusses the HHVBP Model design, the guiding principles to select measures, and the six priority areas of the National Quality Strategy (NQS) we considered for the Model (80 FR 68656 through 68678). Under the HHVBP Model, any measures we determine to be good indicators of quality will be considered for use in the HHVBP Model in future years, and may be added or removed through the rulemaking process. To further our commitment to objectively assess HHVBP quality measures, we are utilizing an implementation contractor that invited a group of measure experts to provide advice on the adjustment of the current measure set for consideration. The contractor convened a technical expert panel (TEP) consisting of 11 panelists with expertise

in home health care and quality measures that met on September 7, 2016, in Baltimore, Maryland and via conference call on December 2, 2016. The TEP discussed developing a composite total change in ADL/IADL measure; a composite functional decline measure; a measure to capture when an HHA correctly identifies the patient's need for mental and behavioral health supervision; and a measure to identify if a caregiver is able to provide the patient's mental or behavioral health supervision, to align with § 409.45(b)(3)(iii) and the Medicare Benefit Policy Manual (Pub. 100-02), Chapter 7, Section 20.2. We discussed each of these potential measures in further detail in the CY 2018 HH PPS proposed rule (82 FR 35336 through 35340), and also discuss in this section of this final rule. While any new measures would be proposed for use in

future rulemaking, we solicited comment on these potential measures now to inform measure development and selection.

As noted in the CY 2017 HH PPS final rule (81 FR 76747), we received several comments expressing concern that the measures under the Model do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. The commenters opined that the value of including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that improvement is not always the goal for each patient and

that stabilization is a reasonable clinical goal for some patients. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. Many commenters objected to the use of improvement measures in the HHVBP Model. We did not receive any specific measures for future consideration as part of those comments. In the CY 2018 HH PPS proposed rule (82 FR 35336 through 35340), we identified measures that we are considering for possible inclusion under the Model in future rulemaking and sought input from the public on the measures described, as well as any input about the development or construction of the measures and their features or methodologies. We are also including the description of these possible measures in this final rule in the subsections that follow.

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

The measure set finalized in the CY 2016 HH PPS final rule included Change in Daily Activity Function as Measured by the Activity Measure for Post-Acute Care (AM-PAC) (NQF #0430). However, the measure was removed in the CY 2017 HH PPS final rule and never used in the HHVBP Model because the measure required use of a proprietary data collection instrument in the home health environment. We stated in the CY 2018 HH PPS proposed rule that we were considering replacing Change in Daily Activity Function as Measured by AM-PAC (NQF #0430) with a composite total ADL/IADL change performance measure. During the September 2016 TEP meeting, an alternative to the Change in Daily Activity Function measure was presented. The TEP requested that a composite Total ADL/IADL Change measure be investigated empirically. This measure was discussed as part of the follow-up conference call, and the TEP supported continued development of the measure in the HHVBP Model as a way of including a measure that captures all three potential outcomes for home health patients: stabilization; decline; and improvement. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity. We noted in the CY 2018 HH PPS proposed rule that we

reviewed this suggested alternative and believe this measure would provide actionable and transparent information that would support HHA efforts to improve care and prevent functional decline for all patients across a broad range of patient functional outcomes. The measure would also improve accountability during an episode of care when the patient is directly under the HHA's care.

We noted in the CY 2018 HH PPS proposed rule that the name of this potential composite measure could be *Total Change in ADL/IADL Performance by HHA Patients*. The measure would report the average, normalized, total improved functioning across the 11 ADL/IADL items on the current OASIS-C2 instrument. The measure is calculated by comparing scores from the start-of-care/resumption of care to scores at discharge. For each item the patient's discharge assessed performance score is subtracted from the patient's start of care/resumption of care assessed performance score, and then divided by the maximum improvement value based on the number of response options for that item. These values are summed into a total normalized change score that can range from -11 (that is, for an episode where there is maximum decline on all 11 items used in the measure) to +11 (that is, for an episode where there is the maximum improvement on all 11 items). An HHA's score on the measure is based on its average across all eligible episodes. Patients who are independent on all 11 ADL/IADL items at Start of Care (SOC)/Resumption of Care (ROC) would also be included in the measure. The HHA's observed score on the measure is the average of the normalized total scores for all eligible episodes for its patients during the reporting period.

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

ADL OASIS-C2 items related to Self-Care:

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

ADL OASIS-C2 items related to Mobility:

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

- M1860 (Ambulation).
- Other IADLs OASIS items:*
- M1880 (Light meal preparation).
 - M1890 (Telephone use).
 - M2020 (Oral medication management).

Based on these identified measures, we would risk-adjust using OASIS-C2 items to account for case-mix variation and other factors that affect functional decline but are outside the influence of the HHA. The risk-adjustment model uses an ordinary least squares (OLS)^{17 18} regression framework because the outcome measure (normalized change in ADL/IADL performance) is a continuous variable.

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

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

Two predictive models, one based on predicted values from CY 2014 and one from CY 2015, were computed. The correlations at the episode level between observed and predicted values for the target outcome measure *Total Change in ADL/IADL Performance by HHA Patients* are shown in Table 16.

¹⁷ Fox, John (1997). *Applied Regression Analysis, Linear Models, and Related Methods*/Edition 1, 1997, SAGE.

¹⁸ Greene, William H. (2017). *Econometric analysis* (8th ed.). New Jersey: Pearson. ISBN 978-0134461366.

TABLE 16—CORRELATIONS AT THE EPISODE LEVEL BETWEEN OBSERVED AND PREDICTED VALUES FOR THE TARGET OUTCOME MEASURE TOTAL CHANGE IN ADL/IADL PERFORMANCE BY HHA PATIENTS

| Data group | Correlation | Significance (p <) | r2 (Coeff. Determination) % |
|----------------------------|-------------|---------------------|-----------------------------|
| CY2014, National | 0.5022 | 0.0001 | 25.22 |
| CY2014, HHVBP states | 0.5094 | 0.0001 | 25.95 |
| CY2015, National | 0.5011 | 0.0001 | 25.11 |
| CY2015, HHVBP states | 0.5076 | 0.0001 | 25.76 |

The results in Table 16 suggest that either model would account for 25 percent or more of the variability in the outcome measure. These models could be considered very strong predictive models for the target outcome measure. Although the analysis supports developing a composite measure, the analysis assumes that the OASIS–C2 items identified to be used in the composite measure do not change. However, we recognize that OASIS–C2 items could be removed or added in any given year. We expect to conduct an additional analysis, in advance of any future proposal, to assess whether changes to OASIS–C2 items that are removed or added could significantly impact a HHA’s ability to address several measures to improve its overall score in the composite measure. We solicited public comments on whether or not to include a composite total ADL/IADL change performance measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

2. Composite Functional Decline Measure

The second measure we are considering for possible inclusion under the Model in future rulemaking is a *Composite Functional Decline Measure* that could be the percentage of episodes where there was decline on one or more of the eight ADL items used in the measure. As noted in the CY 2018 HH PPS proposed rule and this final rule, we received comments on the CY 2017 HH PPS proposed rule suggesting that we consider the addition of stabilization or maintenance measures. We stated in the CY 2018 HH PPS proposed rule that to address this suggestion, we are considering a composite functional decline measure because the existing functional stabilization measures, taken individually, are topped out, with HHA level means of 95 percent or higher. This type of composite functional decline measure is similar to the composite ADL decline measure that is

used in the Skilled Nursing Facility (SNF) Quality Reporting program (QRP).¹⁹ The SNF QRP measure is constructed from four ADL items: Bed mobility; transfer; eating; and toileting.

An HHVBP composite functional decline measure could provide actionable and transparent information that could support HHA efforts to improve care and prevent functional decline for all patients, including those for whom improvement in functional status is not a realistic care goal. We noted in the CY 2018 HH PPS proposed rule that this concept was discussed during the TEP meeting on September 7, 2016, with a follow-up conference call held on December 2, 2016. The TEP supported the inclusion of measures of stabilization and decline in the HHVBP Model, as well as further development of the composite functional decline measure. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity.

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

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

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

¹⁹ “Long-stay Nursing Home Care: Percent of Residents Whose Need for help with Activities of Daily Living has Increased.” <https://www.qualitymeasures.ahrq.gov/summaries/summary/50060>.

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

Across all participating HHAs in the HHVBP Model, for HHAs that had less than 20 percent of episodes lasting more than 60 days, the average on the functional decline measure was 8.08 percent. This increased to 11.08 percent for HHAs with 20 percent to 40 percent of episodes lasting more than 60 days, 14.23 percent for HHAs with 40 percent to 60 percent of episodes lasting more than 60 days, and 20.59 percent for HHAs with more than 60 percent of episodes lasting more than 60 days. This finding suggests that, in addition to focusing on prevention of functional decline, we should also attempt to better predict a patient’s functional trajectory and potentially stratify the population to exclude those on a likely downward trajectory. However, in spite of this finding, the inclusion of a measure that rewards providers for avoiding functional decline has the advantage of diversifying the set of measures for the HHVBP model. We solicited public

comments on whether or not to include a composite functional decline measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

3. Behavioral Health Measures

Although we did not receive comments or suggestions through the rulemaking process for the HHVBP Model regarding behavioral or mental health measures, we noted in the CY 2018 HH PPS proposed rule that we recognize that the Model does not include such measures. The OASIS–C2 collects several items related to behavioral and mental health (M1700 Cognitive Functioning; M1710 Confusion Frequency; M1720 Anxiety; M1730 Depression Screening; M1740 Cognitive, Behavioral, and Psychiatric Symptoms; M1745 Frequency of Disruptive Behavior Symptoms; and M1750 Psychiatric Nursing Services). These items are used to compute both Improvement and Process measures as well as Potentially Avoidable Events. The inclusion of behavioral health measures is important for care transformation and improvement activities as many persons served by the Home Health program may have behavioral health needs.

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

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

We stated in the CY 2018 HH PPS proposed rule that we are considering adding a *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure to the HHVBP Model in the future to capture a patient's need for mental or behavioral health supervision based on an identifier. This identifier is based on information from existing Neuro/Emotional/Behavioral Status OASIS items, along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure assesses whether the HHA correctly identifies whether or not the patient needs mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

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

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

- Was discharged from a psychiatric hospital prior to entering home health care (M1000 = 6).
- Is diagnosed as having chronic mental behavioral problems (M1021 and M1023).
- Is diagnosed with a mental illness (M1021 and M1023).
- Is cognitively impaired (M1700 ≥ 2).
- Is confused (M1710 ≥ 2).
- Is identified as having a memory deficit (M1740 = 1).
- Is identified as having impaired decision-making (M1740 = 2).

- Is identified as being verbally disruptive (M1740 = 3).

- Is identified as being physically aggressive (M1740 = 4).

- Is identified as exhibiting disruptive, infantile, or inappropriate behaviors (M1740 = 5).

- Is identified as being delusional (M1740 = 6).

- Has a frequency of disruptive symptoms (M1745 ≥ 2).

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

- The algorithm identifies the patient as not in need of mental or behavioral health supervision and the HHA identifies the patient as not in need of mental or behavioral health supervision; or

- The algorithm identifies the patient as in need of mental or behavioral health supervision and the HHA identifies the patient as in need of mental or behavioral health supervision; then

- The outcome is coded as 1, successful.

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

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

The prediction model for this outcome measure uses 39 risk factors²⁰ with each risk factor statistically significant at $p < 0.0001$. The correlation for the model between observed and predicted values as estimated by Somers' D²¹ is 0.427, that yields an estimated coefficient of determination (r^2) value based on the Tau-a²² of 0.201. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic.²³ This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The discussed prediction model has a c-statistic equal to 0.713, which is considered to be good. Using data from CY 2015, the episode-level mean for the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure is 61.98 percent, nationally, and 62.98 percent for the HHVBP states.

²⁰ "Home Health Quality Initiative: Quality Measures" <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>

²¹ Somers' D is a statistic that is based on the concept of concordant vs. discordant pairs for two related values. In this case, if both the observed and predicted values are higher than the average or if both values are less than the average, then the pair of numbers is considered concordant. However, if one value is higher than average and the other is lower than average—or vice versa, then the pair of values is considered discordant. The Somer's D is (# of concordant pairs—# of discordant pairs)/total # of pairs. The higher the ratio, the stronger the concordance between the two set of values.

²² The Kendall Tau-a assumes that if there is a correlation between two variables, then sorting the variables based on one of the values will result in ordering the second variable. It uses the same concept of concordant pairs in Somers' D but a different formula: $t = [(4P)/((n)(n-1))] - 1$ where $p = \#$ of concordant pairs and $n = \#$ of pairs. This correlation method reduces the effect of outlier values as the values are essentially ranked.

²³ The C-statistic (sometimes called the "concordance" statistic or C-index) is a measure of goodness of fit for binary outcomes in a logistic regression model. In clinical studies, the C-statistic gives the probability a randomly selected patient who experienced an event (for example, a disease or condition) had a higher risk score than a patient who had not experienced the event. It is equal to the area under the Receiver Operating Characteristic (ROC) curve and ranges from 0.5 to 1.

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

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

We stated in the CY 2018 HH PPS proposed rule that we are considering including under the Model in future rulemaking a *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure that would encourage HHAs to ensure that patients who need mental or behavioral health supervision are receiving such care from the patient's caregivers, and would be a realistic care goal.

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

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

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

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

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

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

We noted in the CY 2018 HH PPS proposed rule that we are considering whether the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure or the Caregiver Can/Does Provide for Patient's Mental or Behavioral Health

Supervision Need measure would be most meaningful to include in the Model. We also noted that we were considering the interactions between the Home Health Grouping Model (HHGM) proposal on quality measures discussed in section III. of the proposed rule and the HHVBP Model for the quality measures discussed in section IV.B of the proposed rule. We solicited public comments on the methodologies, analyses used to test the quality measure, and issues described in this section for future measure considerations. We noted that we will continue to share analyses as they become available with participating HHAs during future webinars.

The following is a summary of the public comments received on the "Quality Measures for Future Consideration" and our responses:

Comment: We received several comments from stakeholders offering their input on the quality measures discussed. Many were receptive to the development of new measures. Some commenters supported the development of composite measures, but believed improvement should not be the sole focus of any measure as they indicated that many patients benefit greatly from skilled home health services but are not likely to improve on these measures. While many commenters were in support of the inclusion of measures that capture an agency's ability to identify mental or behavioral health needs and identify whether a caregiver is available to provide behavioral supervision, they cautioned CMS that home health providers should not be made responsible for determining behavioral health diagnoses outside of a simple recognition of need. MedPAC was one of a few commenters that did not support developing new process measures, such as the described measure concepts of correctly identifying the patient's need for mental and behavioral health supervision, and identifying if a caregiver is able to provide the patient's mental or behavioral health supervision. MedPAC indicated that while it believes that improving a patient's functional ability is a goal of home health care, it has some degree of concern that the 'composite total change in ADL/IADL measure' and the 'composite functional decline measure' represent reporting elements completely within the control of the home health agency. MedPAC recommended that if CMS includes these measures, it may also want to consider and propose ways that such data could be independently audited or otherwise verified. Another commenter opposed the addition of a composite

functional decline measure as they believe it rewards agencies that have selective admission practices of refusing patients that are likely to decline toward end of life, and also opposed the inclusion of behavioral health measures as they believe that they may discourage agencies from accepting patients when there are behavioral health issues or few local resources.

Response: We appreciate the comments on the discussion of the measures that we are considering for possible inclusion in the Model and will take the recommendations into consideration as we determine whether or not to include new measures in future rulemaking.

Comment: In response to our solicitation of public comment, we also received a few comments that were outside the scope of discussion of the specific future quality measures that we are considering, as discussed in the proposed rule. A commenter recommended that CMS develop and implement HHVBP policies in alignment with Congressional activity supporting one national approach to VBP for home care services. Another commenter recommended that CMS factor quality metrics into HHVBP that not only relate to health outcomes, but also that are within the control of the home health care provider, adequately measuring the quality of care provided. Another commenter recommended that CMS ensure that value-based home health purchasing models incorporate a shared definition of value that incorporates the patient and caregiver voice. A few commenters questioned the level of payment at risk under the Model, and believed that placing up to eight percent of HHA payment at risk for performance is too much. A few commenters questioned the geographic participation criteria for the Model and recommended including voluntary participation by interested HHAs in non-participating states.

Response: We appreciate the comment to align home health VBP policies with Congressional activity supporting a national approach to VBP home care services. We also appreciate the comments that recommend adequately measuring the quality of care provided and for CMS to ensure that value-based home health purchasing models incorporate a shared definition of value that incorporates the patient and caregiver voice. As an Innovation Center model, we are closely monitoring the quality measures and will address any needed adjustments through future rulemaking. With respect to the comments regarding the level of payment at risk under the Model, as

discussed in the CY 2016 HH PPS final rule (80 FR 68687), competing HHAs that provide the highest quality of care and that receive the maximum upward adjustment will improve their financial viability that could ensure that the vulnerable population that they serve has access to high quality care. Only HHAs that provide very poor quality of care, relative to the cohort they compete within, would be subject to the highest downward payment adjustments. We appreciate the desire for interested HHAs in non-participating states to participate in the Model, but do not plan to re-open the Model to additional participants at this time.

We appreciate the comments on potential new quality measures and intend to continue to provide opportunities for stakeholder input as we consider additional measures for possible inclusion in the HHVBP Model's applicable measure set. We will continue to collect and analyze data as we consider whether to propose any additional measures in future rulemaking.

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

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary is directed to reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and (except in 2018) further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

We use the terminology "CY [year] HH QRP" to refer to the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for an HHA to avoid a 2 percentage point reduction to its market

basket percentage increase under section 1895(b)(3)(B)(v)(I) of the Act when calculating the payment rates applicable to it for that calendar year.

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

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

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the HH QRP, such as alignment with the CMS Quality

Strategy,²⁴ which incorporates the three broad aims of the National Quality Strategy.²⁵ As part of our consideration for measures for use in the HH QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the home health setting. We have previously adopted measures with the term “Application of” in the names of those measures. We have received questions pertaining to the term “application” and clarified in the proposed rule that when we refer to a measure as an “Application of” the measure, we mean that the measure would be used in a setting other than the setting for which it was endorsed by the NQF. For example, in the FY 2016 SNF PPS Rule (80 FR 46440 through 46444) we adopted An Application of the Measure Percent of Residents with Experiencing Falls with Major Injury (Long Stay) (NQF #0674), which is endorsed for the Nursing Home setting but not the SNF setting. For such measures, we stated that we intend to seek NQF endorsement for the home health setting, and if the NQF endorses one or more of them, we would update the title of the measure to remove the reference to “Application of.”

We received comments on the considerations we apply in our measure selection and on other topics related to measures used in the HH QRP.

Comment: Some commenters supported the standardization of measures and data across HHAs, LTCHs, IRFs, and SNFs so that CMS can make comparisons between them, but cautioned that such standardization could compromise the validity of the data. These commenters stated that the home is different than institutional settings because the patient has a greater role in determining how, when, and if certain interventions are provided, and that 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. Other commenters expressed concerns about the reliability and validity of cross-setting measures due to the unique characteristics of the home health setting and emphasized caution in interpreting measure rates.

Response: We appreciate the support for standardization to enable

comparisons across post-acute care providers. We also recognize the uniqueness of the home setting, including patients’ capacity to directly and independently manage their environment and health care needs, such as medications and treatments. However, we disagree that patients are limited in their freedom to help set their goals and preferences when receiving care services within LTCHs, IRFs or SNFs. In our measure development and alignment work, we continuously assess and account for the unique characteristics of home health patients including the use of risk-adjustment models that account for differences in cognitive and functional ability. Further, we are mindful that regardless of where services are rendered, risk adjustment is generally applied to characteristics of the individual rather than the provider setting.

All of the measures we proposed to adopt for the HH QRP were tested for reliability and/or validity, and we believe that the results of that testing support our conclusion that the measures 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 2018 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>. We will continue to test, monitor and validate these measures as part of measure maintenance.

Comment: One commenter suggested that the claims-based measures be weighted more than OASIS measures in order to control for inflated outcomes. Another commenter was concerned that OASIS measure data can be manipulated and suggested the HH QRP should only use claims-based measures because they are more objective.

Response: We wish to clarify that we do not weight home health measures in the home health quality reporting program. However, we believe that the commenter is concerned about the gaming on behalf of home health agencies. We believe that the collection of both claims-based and OASIS based measures is appropriate for the program. Claims-based data can be limited because they are associated with billing and do not always provide a complete picture of the patient’s health assessment status. OASIS fills in those gaps by giving us additional information about care processes and outcomes that are furnished to HHA patients.

²⁴ <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

²⁵ <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm>.

Although we recognize that OASIS assessments are, by their nature, more subjective than claims, we require HHAs to attest to the accuracy of the data submitted on each OASIS assessment.

C. Accounting for Social Risk Factors in the HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35341 through 35342), we discussed accounting for social risk factors in the HH QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE²⁶) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.²⁷ The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for

measuring and accounting for social risk factors, including stratified public reporting.²⁸

In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. Measures from the HH QRP, Rehospitalization During the First 30 Days of Home Health (NQF# 2380), and Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF# 2505) were included in this trial. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. Since the publication of the CY 2018 HH PPS proposed rule, the National Quality Forum (NQF) has concluded their initial trial on risk adjustment for quality measures. Based on the findings from the initial trial, NQF will continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional 3 years. The extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement.

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

In addition, in the CY 2018 HH PPS proposed rule (82 FR 35341 through 35342), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HH QRP. We note that to the extent we consider making any changes we would propose them through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the methods previously stated will be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also sought comment on operational considerations. We are committed to ensuring that beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs. This section of this final rule includes a discussion of the comments we received on this topic, along with our responses.

Comment: Commenters were generally supportive of accounting for social risk factors in the HH QRP quality measures. Many commenters stated that there was evidence demonstrating that these factors can have substantial influence on patient health outcomes. Some commenters who supported accounting for social risk factors noted that these factors are outside the control of the provider and were concerned that without risk adjustment, differences in quality scores may reflect differences in patient populations rather than differences in quality.

A few other commenters, while acknowledging the influence of social risk factors on health outcomes, cautioned against adjusting for them in quality measurement due to the potential for unintended consequences.

²⁶ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

²⁷ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

²⁸ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

These commenters expressed concern over the possibility that risk-adjusted measures may remove incentives for quality improvement among facilities that serve higher levels of underserved populations.

Regarding risk adjustment methodology, some commenters made specific recommendations regarding the type of risk adjustment that must be used. Commenters stated that any risk stratification must be considered on a measure-by-measure basis, and that measures that are broadly within the control of the provider and reflective of direct care, such as pressure ulcers, must not be stratified. The commenters stated that social risk factor adjustment be used only on outcome measures, not process measures. One commenter alternately suggested using socioeconomic factors to stratify, rather than adjust, measure results. Multiple commenters recommended that we conduct further research and testing of risk-adjustment methods. A commenter suggested that CMS use Social Risk Factors, Social Determinants of Health or Distressed Communities Index scores within the HH QRP. Some commenters suggested the formation of a TEP to further refine the use of such data.

In addition to supporting race and ethnicity, dual eligibility status, and geographical location, commenters suggested additional risk factors, including: Patient-level factors such as lack of personal resources, education level, and employment. Some commenters also suggested community resources and other factors such as access to adequate food, medications, living conditions (including living alone), and lack of an adequate support system or caregiver availability. Several encouraged the development of measures that reflect person-centered domains to improve the focus on outcomes for disadvantaged populations.

A few commenters provided feedback on confidential and public reporting of data adjusted for social risk factors. A commenter suggested that CMS start with confidential reporting and, once there has been opportunity for HHAs to review and understand their results, CMS could transition to public reporting.

Response: We thank commenters for their suggestions. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities. We believe that the path forward must incentivize improvements in health outcomes for disadvantaged

populations while ensuring that beneficiaries have adequate access to excellent care. Also, based on the findings from the initial trial, NQF will continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional three years. The extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement. We await recommendations of the NQF trial to further inform our efforts.

We will consider all suggestions as we continue to assess each measure and the overall HH QRP. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across several quality reporting programs, informed by considerations of stratification methods described in IX.A.13 of the preamble of the FY 2018 IPPS/LTCH PPS final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that will allow us to address disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

D. Removal of OASIS Items

In the CY 2018 HH PPS proposed rule (82 FR 35342) we proposed to remove 247 data elements from 35 OASIS items collected at specific time points during a home health episode. These data elements are not used in the calculation of quality measures already adopted in the HH QRP, nor are they being used for previously established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model or care planning. We included list of the 35 OASIS items we proposed to remove, in part or in their entirety, in Table 45 of the proposed rule (82 FR 35342 and 35343) and also made them available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>. Subsequent to issuing the proposed rule, we discovered that we had inadvertently included three OASIS items in Table 45 that are used either for payment or for the HH QRP. Those items are M1200 Vision (used for payment), M2030 Management of Injectable Medications (used for payment), and M1730 Depression Screening (used in the HH QRP). Accordingly, we will not be removing these items from the OASIS.

Comment: Many commenters supported our proposal to remove items from OASIS. Most of these commenters agreed that items not used for the purposes of determining patient outcomes or the quality of care should be removed.

Response: We appreciate the support for our proposal to remove items from OASIS.

Comment: One commenter noted that OASIS Item M2250 (Plan of Care Synopsis) is proposed for removal and questioned whether OASIS Item M2401 (Intervention Synopsis) will continue to be collected.

Response: We proposed to remove OASIS Item M2250 because it is not used for the HH QRP or for any other purpose. OASIS Item M2401 is used in the calculation of the quality measure Diabetic Foot Care and Patient Education Implemented (NQF #0519), which we adopted in the CY 2010 HH PPS final rule (74 FR 58096), and will therefore continue to be collected at the time point of Transfer to an Inpatient Facility and Discharge from Agency.

Comment: One commenter questioned if there is another OASIS version that will be implemented so that a beneficiary's Medicare Beneficiary Identifier (MBI) can be provided in the OASIS.

Response: Effective January 1, 2018 the OASIS-C2 will be able to accommodate the MBI which is an alternative Medicare Beneficiary Identifier that we are adopting to replace the Social Security number (SSN)-based Health Insurance Claim Number (HICN) in an effort to prevent identity theft in the Medicare population. Instructions for reporting OASIS Item M0063 (Medicare Beneficiary Number) can be found in the OASIS-C2 Guidance Manual: Effective January 1, 2018 at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-Effective_1_1_18.pdf.

Comment: A few commenters raised concerns about the overall burden associated with CMS' proposals, noting that if all proposed new assessment items are finalized, the new assessment items could be more burdensome to collect than the one being removed.

Response: We appreciate the comments and as more fully discussed in section V.H. of this final rule, we have decided not to finalize the standardized patient assessment data elements proposed for three of the five categories under § 1899B(b)(1)(B) of the Act: Cognitive Function and Mental

Status; Special Services, Treatments, and Interventions; and Impairments.

Final Decision: After consideration of the comments received, we are finalizing the removal of 235 data elements from 33 OASIS items collected

at specific time points during a home health episode, effective with all HHA assessments on or after January 1, 2019. As previously explained, we will continue to collect OASIS items M1200, M2030 and M1730. Table 17 lists the

OASIS items and data elements to be removed and they can also be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>.

TABLE 17—ITEMS TO BE REMOVED FROM OASIS EFFECTIVE JANUARY 1, 2019

| OASIS item | Specific time point | | | | | |
|--------------|---------------------|--------------------|-----------|-----------------------------------|---------------|-----------------------|
| | Start of care | Resumption of care | Follow-up | Transfer to an inpatient facility | Death at home | Discharge from agency |
| M0903 | | | | 1 | 1 | 1 |
| M1011 | 6 | 6 | 6 | | | |
| M1017 | 6 | 6 | | | | |
| M1018 | 6 | 6 | | | | |
| M1025 | 12 | 12 | 12 | | | |
| M1034 | 1 | 1 | | | | |
| M1036 | 4 | 4 | | | | |
| M1210 | 1 | 1 | | | | |
| M1220 | 1 | 1 | | | | |
| M1230 | 1 | 1 | | | | 1 |
| M1240 | 1 | 1 | | | | |
| M1300 | 1 | 1 | | | | |
| M1302 | 1 | 1 | | | | |
| M1320 | 1 | 1 | | | | 1 |
| M1322 | | | | | | 1 |
| M1332 | | | | | | 1 |
| M1350 | 1 | 1 | | | | |
| M1410 | 3 | 3 | | | | |
| M1501 | | | | 1 | | 1 |
| M1511 | | | | 5 | | 5 |
| M1610 | | | | | | 1 |
| M1615 | 1 | 1 | | | | 1 |
| M1750 | 1 | 1 | | | | |
| M1880 | 1 | 1 | | | | 1 |
| M1890 | 1 | 1 | | | | 1 |
| M1900 | 4 | 4 | | | | |
| M2030 | | | | | | 1 |
| M2040 | 2 | 2 | | | | |
| M2102* | 6 | 6 | | | | ** 3 |
| M2110 | 1 | 1 | | | | |
| M2250 | 7 | 7 | | | | |
| M2310 | | | | *** 15 | | *** 15 |
| M2430 | | | | 20 | | |
| Total | 70 | 70 | 18 | 42 | 1 | 34 |

* M2102 row f to remain collected at Start of Care, Resumption of Care and Discharge from Agency as part of the HH VBP program.

** M2102 rows a, c, d to remain collected at Discharge from Agency for survey purposes.

*** M2310 responses 1, 10, OTH, UK to remain collected at Transfer to an Inpatient Facility and Discharge from Agency for survey purposes.

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

1. Definition of Standardized Patient Assessment Data

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

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

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.
- Cognitive function, such as ability to express and understand ideas, and mental status, such as depression and dementia.
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy,

central line placement, and total parenteral nutrition.

- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers.
- Impairments, such as incontinence and an impaired ability to hear, see or swallow.
- Other categories deemed necessary and appropriate by the Secretary.

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

(discharge), but the Secretary may require the data to be reported more frequently.

In the CY 2018 HH PPS proposed rule (82 FR 35343), we proposed to define the standardized patient assessment data that HHAs must report under the HH QRP, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in healthcare quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We noted that we intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among healthcare providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation, and identifying comorbidities that might increase the medical complexity of a particular admission.

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

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

Assessment Instrument (IRF-PAI), which is the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC provider types has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across HHAs, LTCHs, IRFs, and SNFs that enables us to make comparisons between them, we proposed to define “standardized patient assessment data” as patient or resident assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply.

We stated in the proposed rule that standardizing the questions and response options across the four PAC assessment instruments is an essential step in making that data interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We did not receive any specific comments on the proposed definition.

Final Decision: We are finalizing as proposed our definition of standardized patient assessment data.

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

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

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, with each team working with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for

each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

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

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

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12 to September 12, 2016 to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

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

Strategy which is framed using the three broad aims of the National Quality Strategy.

3. Policy for Retaining HH QRP Measures and Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76755 through 76756), we adopted a policy that will allow for any quality measure adopted for use in the HH QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension or replacement, we refer readers to the CY 2017 HH PPS final rule (81 FR 76755 through 76756). We proposed to apply this same policy to the standardized patient assessment data that we adopt for the HH QRP.

Comment: Several commenters supported this proposal.

Response: We appreciate the commenters' support.

Final Decision: We are finalizing that our policy for retaining HH QRP measures will apply to the standardized patient assessment data that we adopt for the HH QRP.

4. Policy for Adopting Changes to HH QRP Measures and Application of That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76756), we adopted a subregulatory process to incorporate updates to HH quality measure specifications that do not substantively change the nature of the measure. We noted that substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process

for nonsubstantive changes, we refer readers to the CY 2017 HH PPS final rule (81 FR 76756). We proposed to apply this policy to the standardized patient assessment data that we adopt for the HH QRP. We invited public comment on this proposal.

Comment: One commenter requested that we propose to adopt all substantive changes to measures only after soliciting input from a technical expert panel of home health clinical leaders, holding a Special Open Door Forum to explain the changes under consideration, and allowing stakeholders to submit meaningful comments on those potential changes.

Response: We agree that input from both technical experts and the public is critical to the measure development process, and we generally solicit both types of input when we consider whether to propose substantive updates to measures. We also solicit input in other ways, such as through open door forums and solicitations for public comment, and often engage in these activities prior to proposing substantive updates through the rulemaking process. Finally, the rulemaking process itself gives the public an additional opportunity to comment on the substantive updates to measures under consideration.

Final Decision: After consideration of the public comments, we are finalizing that we will apply our policy for adopting changes to HH QRP measures to the standardized patient assessment data that we adopt for the HH QRP.

5. Quality Measures Previously Finalized for the HH QRP

The HH QRP currently has 23 measures, as outlined in Table 18.

TABLE 18—MEASURES CURRENTLY ADOPTED FOR THE HH QRP

| Short name | Measure name & data source |
|-----------------------|--|
| OASIS-based | |
| Pressure Ulcers | Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF # 0678).* + |
| DRR | Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program. + |
| Ambulation | Improvement in Ambulation/Locomotion (NQF #0167). |
| Bathing | Improvement in Bathing (NQF #0174). |
| Dyspnea | Improvement in Dyspnea. |
| Oral Medications | Improvement in Management of Oral Medication (NQF #0176). |
| Pain | Improvement in Pain Interfering with Activity (NQF #0177). |
| Surgical Wounds | Improvement in Status of Surgical Wounds (NQF #0178). |
| Bed Transferring | Improvement in Bed Transferring (NQF # 0175). |
| Timely Care | Timely Initiation Of Care (NQF # 0526). |
| Depression Assessment | Depression Assessment Conducted. |
| Influenza | Influenza Immunization Received for Current Flu Season (NQF #0522). |
| PPV | Pneumococcal Polysaccharide Vaccine Ever Received (NQF #0525). |
| Falls Risk | Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537). |
| Diabetic Foot Care | Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (NQF #0519). |
| Drug Education | Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care. |
| Claims-based | |
| MSPB | Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP). + |

TABLE 18—MEASURES CURRENTLY ADOPTED FOR THE HH QRP—Continued

| Short name | Measure name & data source |
|----------------------------------|--|
| DTC | Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP). + |
| PPR | Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program. + |
| ACH | Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171). |
| ED Use | Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173). |
| Rehospitalization | Rehospitalization During the First 30 Days of Home Health (NQF #2380). |
| ED Use without Readmission | Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505). |
| HHCAHPs-based | |
| Professional Care | How often the home health team gave care in a professional way. |
| Communication | How well did the home health team communicate with patients. |
| Team Discussion | Did the home health team discuss medicines, pain, and home safety with patients. |
| Overall Rating | How do patients rate the overall care from the home health agency. |
| Willing to Recommend | Will patients recommend the home health agency to friends and family. |

* Not currently NQF-endorsed for the home health setting.
 The data collection period will begin with CY 2017 Q1&2 reporting for CY 2018 APU determination, followed by the previously established HH QRP use of 12 months (July 1, 2017–June 30, 2018) of CY 2017 reporting for CY 2019 APU determination. Subsequent years will be based on the HH July 1–June 30 timeframe for APU purposes. For claims data, the performance period will use rolling CY claims for subsequent reporting purposes.

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

In the CY 2018 HH PPS proposed rule (82 FR 35345) we proposed that beginning with the CY 2020 HH QRP, in addition to the quality measures we are retaining under our policy described in section V.B. of this final rule, we would replace the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) with a modified version of the measure and adopt one measure on patient falls and one measure on assessment of patient functional status. We also proposed to characterize the data elements described in this section as standardized patient assessment data under section 1899B(b)(1)(B) of the Act that must be reported by HHAs under the HH QRP through the OASIS. The new measures that we proposed to adopt are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674).
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

The measures are described in more detail as follows:

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

a. Measure Background

We proposed to remove the current pressure ulcer measure, Percent of

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

b. Measure Importance

As described in the CY 2016 HH PPS final rule (80 FR 68697), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the HH QRP, we referred readers to the CY 2016 HH PPS final rule (80 FR 68697 to 68700).

We proposed to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful and are often an avoidable outcome of

medical care.^{29 30 31 32 33 34} Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long term care settings with appropriate medical care.³⁵ Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.^{36 37}

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by our measure development contractor indicated that adding unstageable pressure ulcers to the quality measure numerator would result in a higher

²⁹ Casey, G. (2013). “Pressure ulcers reflect quality of nursing care.” *Nurs NZ* 19(10): 20–24.
³⁰ Gorzoni, M.L. and S.L. Pires (2011). “Deaths in nursing homes.” *Rev Assoc Med Bras* 57(3): 327–331.
³¹ Thomas, J.M., et al. (2013). “Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.” *J Am Geriatr Soc* 61(6): 902–911.
³² White-Chu, E.F., et al. (2011). “Pressure ulcers in long-term care.” *Clin Geriatr Med* 27(2): 241–258.
³³ Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med*. 2001;135 (8 Part 2), 744–51.
³⁴ Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.
³⁵ Black, Joyce M., et al. “Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.” *Ostomy-Wound Management* 57.2 (2011): 24.
³⁶ Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. *Ostomy Wound Management* 59(9) <http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien>.
³⁷ Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. *Ostomy Wound Management* 51(4) <http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury>.

percentage of patients with new or worsened pressure ulcers in HHA settings and increase the variability of measure scores. A higher percentage indicates lower quality. This increased variability serves to improve the measure by improving the ability of the measure to distinguish between high and low quality home health agencies.

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

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

distinguish between poor and high performing HHAs.

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

c. Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, including the feasibility of implementing the proposed measure's updates across PAC settings. The TEP supported the use of the proposed measure across PAC settings, including the use of different data elements for measure calculation. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13, and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.^{38 39} Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the

³⁸ Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf>.

³⁹ Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf>.

observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the proposed quality measure to discriminate between poor- and high-performing agencies.

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

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

The public comment summary report for the proposed measure is available on the CMS Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

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

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

d. Data Collection

The data for this quality measure will be collected using the OASIS data set, which is currently submitted by HHAs

through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the OASIS data set. In addition, our proposal to eliminate duplicative data elements that were used in calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for HHAs for the proposed measure. For more information on OASIS data set submission using the QIES ASAP System, we refer readers to <https://www.qtsa.com/>.

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

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

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

Comment: Several commenters supported the proposed replacement of the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. One of these commenters noted that this measure will increase the number of identified pressure ulcers.

One commenter supported the proposed measure calculation approach

because it does not include pressure ulcers that were present at the time of admission, and noted that a pressure ulcer that is present on admission is only included in the measure if it subsequently worsens during the home health episode of care.

Response: We appreciate the commenters’ support.

Comment: A few commenters suggested that we make additional refinements to the proposed measure before we adopt it for the HH QRP; however, these commenters did not specifically describe any proposed refinements. One commenter stated generally that the measure was not fully developed. Another commenter expressed concerns about the differences between the specifications for this measure in the SNF setting related to other PAC settings, including the home health setting. A few commenters additionally commented on the reliability and validity of the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. Some commenters requested that additional testing analyses be conducted prior to the implementation of this measure, and others recommended that we conduct additional testing to determine the applicability of this measure for its use in the home health setting. One commenter encouraged CMS to continue to test the measure to ensure it collects accurate data.

Response: We believe that the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is a fully developed measure that is standardized across the PAC settings, including in the SNF setting. Testing results for this measure indicated increased observed pressure ulcer scores in the LTCH, IRF, SNF and HH patient populations when the unstageable ulcers were included, compared with the previously implemented pressure ulcer measure. Specifically, an analysis conducted by the measure development contractor, using data from October through December 2016, showed mean scores increasing by 2.03 percentage points in home health, with the addition of unstageable pressure ulcers in the measure. The changes in the proposed measure also increased the variability of measures scores.

Further, the reliability and validity of the M0300/M1311 data elements used to calculate this quality measure have been tested in several ways. The MDS 3.0 pilot test showed good reliability in the SNF setting, and we believe that the results are applicable to other post-acute care providers, including HHAs, because the data elements are

standardized across the LTCH, IRF, SNF, and HH settings. Testing conducted to evaluate our ability to derive the measure's numerator from the M0300 data elements revealed that accuracy improved. The M0300 data elements are standardized with the M1311 data elements used in OASIS, and we are able to determine that we can also reliably use M1311 data elements to calculate the measure. Additionally, with regard to the reliability of the pressure ulcer data elements, the average gold-standard to gold-standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate "almost perfect" agreement using the Landis and Koch standard for strength of agreement.⁴⁰

A main difference between the current and proposed pressure ulcer measures is that the proposed measure includes unstageable pressure ulcers, including DTIs, in the numerator of the quality measure, resulting in increased scores in all settings. By including pressure ulcers that were not included in the numerator of the current pressure ulcer measure, the scores on the proposed measure are higher and the risk of the measure being "topped-out" is lower.

To assess the construct validity of this measure, or the degree to which the measure assesses what it claims or purports to be assessing, our measure contractor sought input from TEPs over the course of several years. Most recently, on July 18, 2016, a TEP supported the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers/injuries due to a non-removable dressing or device, and new DTIs. The measure testing activities were presented to TEP members for their input on the reliability, validity, and feasibility of the proposed measure and the changes. The TEP members supported the measure construct.

We intend to continue to perform reliability and validity testing to ensure that that the measure demonstrates scientific acceptability (including reliability and validity) and meets the goals of the HH QRP. Further, while we intend to validate the data collected to ensure data accuracy, we note that providers are expected to submit accurate data. Finally, as with all measure development and

implementation, we will provide training and guidance prior to implementation of the measure to promote consistency in the interpretation of the measure.

Comment: A few commenters suggested that we monitor the measure for unintended consequences such as surveillance bias, suggesting that this could affect measure performance.

Response: We appreciate the comments pertaining to unintended consequences, including potential bias in reporting the number and stage of pressure ulcers, which could affect measure performance. We intend to monitor measure results and item-level responses on an ongoing basis to identify potential biases or other issues.

Comment: Some commenters expressed concerns pertaining to the importance of appropriate documentation of unstageable pressure ulcers, including deep tissue injuries (DTIs). One commenter commented that the definition of pressure ulcers included in the measure may be too subjective to collect reliable, accurate measure data across post-acute care providers, citing DTIs specifically. This commenter added that, as a result, the measure could provide misleading portrayals of HH performance.

Response: We appreciate the comments pertaining to the concerns related to appropriate documentation and definition of unstageable pressure ulcers. We interpret the commenters' comment regarding appropriate documentation of unstageable pressure ulcers in the medical record to mean that as a result of this measure, providers should ensure such documentation is incorporated into the medical record. We note that accurate assessment and documentation of all patient assessment findings is customary for ensuring quality care.

We agree that unstageable pressure ulcers should be appropriately documented, but disagree that the definition of pressure ulcers used in the measure may be too subjective to allow for accurate and reliable data capture in post-acute care settings. The definitions of the pressure-related ulcers and injuries used in this measure are standardized and, while all healthcare assessment information can invoke clinical subjectivity, we believe that the definitions provided in our guidance manuals, which align with nationally recognized definitions, enables the collection of data in a reliable manner. We are also confident, based on the reliability testing results previously explained, that the measure can accurately assess HHA performance. Further, we intend to provide training to

HHAs to ensure that they understand how to properly report it.

Comment: Some commenters requested training, help desk support, and guidance in completing the items that will be used to calculate the proposed measure. One commenter also recommended that CMS conduct training on steps HHAs can take to improve quality.

Response: We are currently engaged in efforts to provide educational activities related to the HH QRP, including training events and responses to questions submitted to the Help Desk, which will include information to help HHAs understand how to complete and code the pressure ulcer. Such educational and training information is part of our ongoing strategy to ensure successful implementation of the HH QRP, and ultimately quality improvement. Recordings of previous trainings are available on the CMS YouTube Web site at <https://www.youtube.com/user/CMSHHSgov/featured>, and we will continue to make recordings of trainings available there. We invite HHAs to submit specific inquiries related to the coding of the OASIS through our help desk, HHQualityQuestions@cms.hhs.gov. Additionally, a Frequently Asked Questions document is provided quarterly for the HH QRP, in the Downloads section of the HH Quality Reporting FAQs Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HH-Quality-Reporting/HH-Quality-Reporting-FAQs-.html>. These FAQ documents are updated to reflect current guidance related to the HH QRP, including data submission deadlines and training materials.

Comment: One commenter noted the proposed measure requires HHAs to count the number of unhealed pressure ulcers at each stage and subtract the number present upon admission. While the commenter agreed that excluding pressure ulcers that are present on admission is an appropriate improvement to the measure, the commenter cautioned that it adds complexity to the coding process. Other commenters stated that this information may be difficult for providers to capture because of the new data elements used to calculate the new measure.

Response: We disagree that the proposed measure will require HHAs to make adjustments to their coding processes because HHAs already submit the data to calculate the modified measure. Additionally, the assessment does not require HHAs to tally or count the number of unhealed pressure ulcers. We perform that calculation for

⁴⁰ Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159-174. Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159-174.

purposes of calculating the measure rates.

Comment: Several commenters recommended that CMS attain NQF endorsement of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure prior to implementation.

Response: While this measure is not currently endorsed by a consensus-based entity, which is currently the National Quality Forum (NQF), we believe that this measure possess the attributes necessary for such endorsement, including the measure's applicability, face validity and feasibility, and its reliability and validity as derived from the national testing. Therefore, we believe that this measure is appropriate for adoption into the HH QRP. However, we intend to submit this measure to NQF for consideration for its consideration for endorsement as soon as feasible.

Comment: A few commenters provided feedback on the use of the term "pressure injury". Commenters encouraged CMS to use the terminology recommended by NPUAP and to align with their staging definitions, which will assist providers to be more standardized.

Response: We have integrated the current language of NPUAP terminology for coding the patient and resident assessment instruments, especially in light of the recent updates made by the NPUAP to their Pressure Ulcer Staging System. The NPUAP announced a change in terminology to use the term "pressure injury" in April 2016.⁴¹ A TEP held by our measure development contractor on July 15, 2016, was supportive of using the term "pressure injury." Some members of the TEP stated that the term "injury" is not associated with blame or harm by an entity, that "injury" may be a more inclusive term than "ulcer", and that the term "pressure injury" may be more easily and positively understood by patients, residents, and family members than "pressure ulcer." The TEP recommended training for providers and consumers regarding any change in terminology. This change will be accompanied by additional training and guidance for providers, patients, or residents to clarify any confusion.

Comment: One commenter suggested that the burden of replacing the current

measure with the modified pressure ulcer measure will be greater than the burden associated with reporting the current pressure ulcer measure. The commenter encouraged CMS to streamline reporting and reduce duplicative efforts. The commenter further commented that CMS should review the total number of data points, including the OASIS measure set, to eliminate HHA documentation and administrative burden.

Response: We appreciate the commenter's feedback. We do not believe that the reporting of the proposed measure will impose a new burden on HHAs because the measure is calculated using data elements that are currently included in OASIS that HHAs already submit. As we continue to refine and modify the OASIS, we will continue to evaluate and avoid any unnecessary burden associated with the implementation of the HH QRP.

Final Decision: After consideration of the comments received, we are finalizing our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, effective with the CY 2020 HH QRP.

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

a. Measure Background

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

provides evidence that a care plan with a goal has been established for the HH patient.

The National Committee on Vital and Health Statistics' Subcommittee on Health,⁴² noted that "information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations in other words, their functional status." This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,⁴³ as well as the risk of nursing home placement and hospitalization of older adults living in the community.⁴⁴ For example, many patients who utilize HH services may be at risk for a decline in function due to limited mobility and ambulation.⁴⁵ Thus, impairment in function activities such as self-care and mobility is highly prevalent in HH patients. For example, in 98 percent of the over six million HH episodes in 2015, the patient had at least one limitation or was not completely independent in self-care activities such as grooming, upper and lower body dressing, bathing, toilet hygiene, and/or feeding/eating.⁴⁶

The primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute setting, and/or facilitate transition to end-of-life care as appropriate.^{47 48}

⁴² Subcommittee on Health National Committee on Vital and Health Statistics, "Classifying and Reporting Functional Status" (2001).

⁴³ Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. Archives of Physical Medicine and Rehabilitation, 2010; 91:345–350.

⁴⁴ Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

⁴⁵ Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

⁴⁷ Riggs, J.S. & Madigan, E.A. (2012). Describing variation in home health care episodes for patients with heart failure. Home Health Care Management and Practice, 24(3): 146–152.

⁴⁸ Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

⁴¹ National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury. The National Pressure Ulcer Advisory Panel—NPUAP. (2016, April 13), from <http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/>.

Home health care can positively impact functional outcomes. In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved ADL function and gait performance.⁴⁹ Home health services, delivered by a registered nurse, positively impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body, bathing meal preparation, shopping, and housekeeping. For some home health patients, achieving independence within the living environment and improved community mobility might be the goal of care. For others, the goal of care might be to slow the rate of functional decline to avoid institutionalization.⁵⁰

Patients' functional status is associated with important patient outcomes, so measuring and monitoring the patients' extent of engaging in self-care and mobility is valuable. Functional decline among the elderly;⁵¹ and chronic illness comorbidities, such as chronic pain among the older adult population^{52 53} are associated with decreases in self-sufficiency and patient activation (defined as the patient's knowledge and confidence in self-managing their health). Impaired mobility, frailty, and low physical activity are associated with institutionalization,⁵⁴ higher risk of falls and falls-related hip fracture and death,^{55 56} greater risk of under

nutrition,⁵⁷ higher rates of inpatient admission from the emergency department,⁵⁸ and higher prevalence of hypertension and diabetes.⁵⁹

In addition, the assessment of functional ability and provision of treatment plans directed toward improving or maintaining functional ability could impact health care costs. Providing comprehensive home health care, which includes improving or maintaining functional ability for frail elderly adults, can reduce the likelihood of hospital readmissions or emergency department visits, leading to reduced health care service expenditures.^{60 61 62} Reducing preventable rehospitalizations, which made up approximately 17 percent of Medicare's \$102.6 billion in 2004 hospital payments, creates the potential for large health care cost savings.^{63 64}

between difficulties in daily activities and falling: loco-check as a self-assessment of fall risk. *Interactive Journal of Medical Research*, 5(2), e20. <https://doi.org/10.2196/ijmr.5590>.

⁵⁶ Zaslavsky, O., Zelber-Sagi, S., Gray, S. L., LaCroix, A. Z., Brunner, R.L., Wallace, R.B., . . . Woods, N.F. (2016). Comparison of Frailty Phenotypes for Prediction of Mortality, Incident Falls, and Hip Fracture in Older Women. *Journal of the American Geriatrics Society*, 64(9), 1858–1862. <https://doi.org/10.1111/jgs.14233>.

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

⁵⁸ Hominick, K., McLeod, V., & Rockwood, K. (2016). Characteristics of older adults admitted to hospital versus those discharged home, in emergency department patients referred to internal medicine. *Canadian Geriatrics Journal* 202F: CGJ, 19(1), 9–14. <https://doi.org/10.5770/cgj.19.195>.

⁵⁹ Halaweh, H., Willen, C., Grimby-Ekman, A., & Svantesson, U. (2015). Physical activity and health-related quality of life among community dwelling elderly. *J Clin Med Res*, 7(11), 845–52.

⁶⁰ Hirth, V., Baskins, J., & Dever-Bumba, M. (2009). Program of all-inclusive care (PACE): Past, present, and future. *Journal of the American Medical Directors Association*, 10, 155–160.

⁶¹ Mukamel, D.B., Fortinsky, R.H., White, A., Harrington, C., White, L.M., & Ngo-Metzger, Q. (2014). The policy implications of the cost structure of home health agencies. *Medicare & Medicaid Research Review*, 4(1). <https://doi.org/10.5600/mmrr2014-004-01-a03>.

⁶² Meunier, M.J., Brant, J.M., Audet, S., Dickerson, D., Gransbery, K., & Ciernins, E.L. (2016). Life after PACE (Program of All-Inclusive Care for the Elderly): A retrospective/prospective, qualitative analysis of the impact of closing a nurse practitioner centered PACE site. *Journal of the American Association of Nurse Practitioners*. <https://doi.org/10.1002/2327-6924.12379>.

⁶³ Jencks, S.F., Williams, M.V., and Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. *New England Journal of Medicine*; 360(14):1418–28.

⁶⁴ Tao, H., Ellenbecker, C.H., Chen, J., Zhan, L., & Dalton, J. (2012). The influence of social environmental factors on rehospitalization among patients receiving home health care services. *ANS*.

Further, improving and maintaining functional ability in individuals with high needs, defined as those with three or more chronic conditions, may also account for an increase in healthcare savings. Adults with three or more chronic conditions have nearly four times the average annual per-person spending for health care services and prescription medications than the average for all U.S. adults, and high needs adults with limitations in their ability to perform ADLs, have even higher average annual health care expenditures.⁶⁵ High needs individuals with functional limitations spend, on average, \$21,021 on annual health care services, whereas the average annual health care expenditures for all U.S. adults are approximately \$4,845.45.

b. Measure Importance

The majority of individuals who receive PAC services, including care provided by HHAs, SNFs, IRFs, and LTCHs, have functional limitations, and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.⁶⁶ The patient populations treated by HHAs, SNFs, IRFs, and LTCHs vary in terms of their functional abilities. For example, for home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home health patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.⁶⁷ The clinical practice guideline *Assessment of Physical Function*⁶⁸ recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge, as well as establishing a functional goal for discharge as part of the care plan is an

Advances in Nursing Science, 35(4), 346–358. <https://doi.org/10.1097/ANS.0b013e318271d2ad>.

⁶⁵ Hayes, S.L., Salzberg, C.A., McCarthy, D., Radley, DC, Abrams, M.K., Shah, T., and Anderson, G.F. (2016). High-Need, High-Cost Patients: Who are they and how do they use health care—A population-based comparison of demographics, health care use, and expenditures. The Commonwealth Fund.

⁶⁶ Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

⁶⁷ Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Vol 1.

⁶⁸ Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). *Evidence-based geriatric nursing protocols for best practice*. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

⁴⁴ Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. *Medical Care Research and Review*, 57; 3: 259–297.

⁴⁵ Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

⁴⁷ Riggs, J.S. & Madigan, E.A. (2012). Describing variation in home health care episodes for patients with heart failure. *Home Health Care Management and Practice*, 24(3): 146–152.

⁴⁸ Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). *Patient safety and quality: an evidence-based handbook for nurses*. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

⁴⁹ Asiri, F.Y., Marchetti, G.F., Ellis, J.L., Otis, L., Sparto, P.J., Watzlaf, V., & Whitney, S.L. (2014). Predictors of functional and gait outcomes for persons poststroke undergoing home-based rehabilitation. *Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association*, 23(7), 1856–1864. <https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.02.025>.

⁵⁰ Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). *Patient safety and quality: an evidence-based handbook for nurses*. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

⁵¹ Gleason, K.T., Tanner, E.K., Boyd, C. M., Saczynski, J.S., & Szanton, S. L. (2016). Factors associated with patient activation in an older adult population with functional difficulties. *Patient Education and Counseling*, 99(8), 1421–1426.

important aspect of patient or resident care across PAC settings.

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

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

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3."⁶⁹ Reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration (PAC-PRD), and we concluded that the functional status

items have acceptable reliability and validity. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. A description of the testing methodology and results are available in several reports, including the report entitled "The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3"⁷⁰ and the report entitled "The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3."⁷¹ These reports are available on our Post-Acute Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

Additional testing of these functional assessment items was conducted in a small field test occurring in 2016–2017, capturing data from 12 HHAs. Preliminary data results yielded moderate to substantial reliability for the self-care and mobility data items. More information about testing design and results can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>.

The functional status quality measure we proposed to adopt beginning with the CY 2020 HH QRP is a process quality measure that is an application of the NQF-endorsed quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a functional treatment goal.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized patient assessment data elements, which assess specific functional activities, such as self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the patient's level of independence with the activity at both admission and discharge. A higher score

indicates more independence. These functional assessment data elements will be collected at Start or Resumption of Care (SOC/ROC) and discharge.

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

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

c. Stakeholder Feedback

Our measures contractor convened a TEP on October 17 and October 18, 2016. The TEP was composed of a diverse group of stakeholders with HH, PAC, and functional assessment expertise. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure of reliability and validity. The TEP additionally provided feedback on the clinical assessment items used to calculate the measure. The TEP reviewed the measure "Percent of Long-Term Care Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF 2631)" for potential application to the home health setting. Overall they were supportive of a functional process measure, noting it could have the positive effect of focusing clinician attention on functional status and goals. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

⁶⁹ Barbara Gage et al., "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set" (RTI International, 2012).

⁷⁰ Ibid.

⁷¹ Ibid.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 4, 2016 through December 5, 2016. Several stakeholders and organizations supported this measure for implementation and for measure standardization. Some commenters also provided feedback on the standardized patient assessment data elements used to calculate the proposed quality measure. Commenters offered suggestions, including providing education regarding the difference in measure scales for the standardized items relative to current OASIS functional items, and guidance on the type of clinical staff input needed to appropriately complete new functional assessment items. Commenters also addressed the feasibility of collecting data for the individual standardized self-care and mobility items in the home health setting. Finally, commenters noted the importance of appropriate goal setting when functional improvement for a patient may not be feasible. The public comment summary report for the proposed measure is available on the CMS Web site at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

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

We reviewed the NQF’s consensus endorsed measures and were unable to identify any home health measures that address functional assessment and treatment goals that address function. However, we were able to identify five functional measures in home health that assess functional activities only, without a treatment goal. These measures are: (1) Improvement in Ambulation/Locomotion (NQF #0167); (2) Improvement in Bathing (NQF #0174); (3) Improvement in Bed

Transfer (NQF #0175); (4) Improvement in Management of Oral Medications (NQF # 0176); and (5) Improvement in Pain Interfering with Activity (NQF #0177). Our review determined that these setting-specific measures are not appropriate to meet the specified IMPACT Act domain as they do not include standardized items or are not included for various other PAC populations. Specifically—

- The items used to collect data for the current home health measures are less specific, leading to broader measure results, whereas the standardized patient assessment data items used for the proposed measure assess core activities such as rolling in bed, walking a specified distance, or wheelchair capability.

- The item coding responses are more detailed when compared to the non-standardized OASIS item responses, allowing for more granular data for the measure.

- The proposed functional measure will capture a patient’s discharge goal at admission into home health; this detail is not captured in the existing endorsed HH function measures.

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

For technical information about the proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we referred readers to the document titled, *Final Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

d. Data Collection

For purposes of assessment data collection, we proposed to add new functional status items to the OASIS, to be collected at SOC/ROC and discharge. These items will assess specific self-care and mobility activities, and will be based on functional items included in the PAC-PRD version of the CARE Item Set. More information pertaining to item testing is available on our Post-Acute

Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

To allow HHAs to fulfill the requirements of the Home Health Agency Conditions of Participation (HHA CoPs) (82 FR 4509), we proposed to add a subset of the functional assessment items to the OASIS, with collection of these items at Follow-Up (FU). The collection of these assessment items at FU by HHAs will allow them to fulfill the requirements outlined in the HHA CoPs that suggest that the collection of a patient’s current health, including functional status, be collected on the comprehensive assessment.

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

Because of the differences between the current function assessment items (OASIS C-2) and the proposed function assessment items that we would collect for purposes of calculating the proposed measure, we would require that HHAs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current OASIS ADL and IADL items, and as discussed previously, we do not believe that the

items are duplicative. However, we solicited comment on opportunities to streamline reporting to avoid duplication and minimize burden.

We proposed that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We referred readers to section V.F.2 of the proposed rule (82 FR 35345 through 35353) for more information on the proposed data collection and submission timeline for this proposed quality measure. We noted that if this measure is finalized, we intended to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure.

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

Comment: A number of commenters supported the proposed measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). MedPAC acknowledged the value of a functional status quality measure that would be standardized with other functional status quality measures across the four PAC settings.

Response: We appreciate the commenters' support of the measure.

Comment: Some commenters suggested that CMS refine the measure and conduct additional testing for home health setting applicability before adopting it. Other commenters recommended that we provide training and give HHAs time to adjust their workflow to both accommodate the new measure and the removal of duplicative data elements in the OASIS. Further, a few commenters expressed concern over the addition of the items used to calculate the proposed process quality measure, claiming that the items will be duplicative and that the legacy items must be removed from the OASIS-C2 assessment instrument to limit provider burden. Commenters also requested that CMS consider the additional resources providers will need to accommodate item set changes and encouraged ongoing education efforts for new data elements.

Response: The items for this measure were rigorously tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD). Based on testing from the PAC PRD, the inter-rater reliability of the items needed to calculate this

measure was favorable, with items' kappa scores between 0.59 and 0.80. This is important for measuring progress in some of the most complex cases treated in post-acute care settings. The data elements developed to calculate this proposed process measure were also tested in a comprehensive field test of existing and potential OASIS data elements and found to be feasible with acceptable levels of inter-rater reliability, as described at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>.

Although HHAs will need to incorporate the data on this measure into their workflow, we do not believe that these data elements are duplicative of other data already collected. The items needed to calculate the proposed measure different assessment scales, coding options for those with medical complexities, and have different definitions for items and activities, and the proposed measure's data elements evaluate usual performance in various manners. Further, to reduce potential burden associated with collecting the proposed measure, we have included several mechanisms to reduce the number of items that apply to any one patient. For example, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the patient does not walk or does not use a wheelchair, respectively.

Comment: Commenters provided feedback on the reliability and validity of the items necessary to calculate the function process measure. Some of these commenters expressed concern that the proposed function measure has not undergone testing and validation in the home health setting or may not be applicable for home health setting as in the facility-based post-acute care settings. One of these commenters expressed concern that the scales used to assess the items for the proposed process quality measure and the current OASIS functional assessment items are different, which could affect the items' reliability and validity. Another commenter raised concern with the difference in timeframe allowed for data collection when compared to other OASIS items.

Response: In the PAC PRD, the functional activity items (self-care and mobility) were tested sufficiently in HHAs and with sufficient patients to support reliability. The functional assessment items were compared to other functional assessment instrument data (including OASIS functional assessment items), as part of the PAC-

PRD analyses with positive results. The inter-rater reliability of the functional activity items has been tested and the results have been favorable with items' kappa scores between .59 and .80. We also conducted analyses of the internal consistency of the function data analyses which indicate moderate to substantial agreement suggesting sufficient reliability for the items used to calculate the proposed process quality measure.

We acknowledge that the scale for the items used to calculate the proposed quality measure vary from the scales that are used in current OASIS-C2 items. The scale used to assess the items for the proposed process quality measure assesses independence in functional activities (a higher score indicates greater independence). We believe that the 6-level scale will allow us to better distinguish change at the highest and lowest levels of patient functioning by documenting minimal change from no change at the low end of the scale.⁷² The PAC PRD supported the use of the scale in HHAs with both the alpha testing and beta testing reinforcing the clinical logic and consistency of language for the functional assessment items. The items in section GG were developed with input from clinicians and stakeholders to better measure the change in function, regardless of the severity of the individual's impairment.

The items used to calculate the proposed process quality measure are standardized across the four PAC settings, based on the need for data to reflect the patient's status at the time of SOC/ROC and EOC. We are currently conducting testing across the four PAC settings to align the most appropriate time frame of data collection at admission/SOC and at discharge/EOC.

A full description of the analyses and the results are provided in the report, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set and Current Assessment Comparisons Volume 3 of 3, and the report is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>. Additional testing of the Section GG items with the OASIS functional items was recently completed

⁷² Barbara Gage *et al.*, "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set" (RTI International, 2012).

and will to continue to help inform guidance for HH providers.

Comment: One commenter suggested that the OASIS should include an assessment of Instrumental Activities of Daily Living (IADL) as a part of functional assessment.

Response: We appreciate the commenter's recommendation and will take it into consideration in future measure refinement work.

Comment: Commenters expressed concern about different clinical staff assessing functional status and setting functional goals across PAC settings, noting that in some settings, such as SNFs, licensed physical therapists typically assess function and set functional goals, whereas in HHAs, nurses typically perform that assessment. Commenters noted that setting a goal will pose a challenge for nurses in the home health setting.

Response: We are unclear why the commenters believe that goal setting will be more difficult in the home health setting than in other settings. The goals being assessed through the measure are intended to be set by patients, not clinicians. In addition, the original testing of the assessment items used for the proposed measure included a wide variety of clinicians to assess item collection, coding and reliability. For more information on testing results, we refer readers to the PAC PRD final report located at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Sheet-Volume-1-of-3.pdf>.

Final Decision: After consideration of the comments received, we are finalizing, as proposed, the adoption of the measure entitled the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) for the HH QRP beginning with the CY 2020 program year.

3. Addressing the IMPACT Act Domain of "Incidence of Major Falls" Measure: Percent of Residents Experiencing One or More Falls With Major Injury

a. Measure Background

Section 1899B(c)(1)(D) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i)(IV) of the Act is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a measure to address

the domain of incidence of major falls, including falls with major injury. We proposed to adopt the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), for which we would begin to collect data on January 1, 2019 for the CY 2020 HH QRP to meet this requirement. This proposed outcome measure reports the percentage of patients who have experienced falls with major injury during episodes ending in a 3-month period.

b. Measure Importance

Falls affect an estimated 6 to 12 million older adults each year and are the leading cause of both fatal injury and nonfatal hospital admissions.^{73 74} Within the home health population, the risk of falling is significant as approximately one third of individuals over the age of 65 experienced at least one fall annually.⁷⁵ Major fall-related injuries among older community-dwelling adults are a growing health concern within the United States^{76 77} because they can have high medical and cost implications for the Medicare community.⁷⁸ In 2013, the direct medical cost for falls in older adults was \$34 billion⁷⁹ and is projected to increase to over \$101 billion by 2030 due to the aging population.⁸⁰

Evidence from various studies indicates that implementing effective fall prevention interventions and

minimizing the impact of falls that do occur reduces overall costs, emergency department visits, hospital readmissions, and overall Medicare resource utilization.^{81 82 83 84} In the 2006 Home Assessments and Modification study, a home visit by an occupational therapist or home care worker to identify and mitigate potential home hazards and risky behavior, resulted in a 46 percent reduction in fall rates for those receiving the intervention compared to controls.⁸⁵ Overall, patients participating in interventions experienced improved quality of life due to reduced morbidity, improved functional ability and mobility, reduced number of falls and injurious falls, and a decrease in the fear of falling.^{86 87} Falls also represent a significant cost burden to Medicare. Each year, 2.8 million older people are treated in Emergency Departments for fall related injuries and over 800,000 require hospitalization.⁸⁸ Adjusted to 2015 dollars, nationally, direct medical costs for nonfatal fall related injuries in older adults were over \$31.3 billion.⁸⁹ Additional health care costs (in 2010 dollars) can range from \$3,500 for a fall without serious injury to \$27,000 for a

⁸¹ Bamgbade, S., & Dearmon, V. (2016). Fall prevention for older adults receiving home healthcare. *Home Healthcare Now*, 34(2), 68–75.

⁸² Carande-Kulis, V., Stevens, J.A., Florence, C.S., Beattie, B.L., & Arias, I. (2015). A cost-benefit analysis of three older adult fall prevention interventions. *Journal of Safety Research*, 52, 65–70. doi:10.1016/j.jsr.2014.12.007.

⁸³ Cohen, A.M., Miller, J., Shi, X., Sandhu, J., & Lipsitz, A. (2015). Prevention program lowered the risk of falls and decreased claims for long-term care services among elder participants. *Health Affairs*, 34(6), 971–977.

⁸⁴ Howland, J., Shankar, K.N., Peterson, E.W., & Taylor, A.A. (2015). Savings in acute care costs if all older adults treated for fall-related injuries completed matter of balance. *Injury Epidemiology*, 2(25), 1–7.

⁸⁵ Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. *Journal of the American Geriatrics Society*. 2011;59(1):26–33.

⁸⁶ Chase, C.A., Mann, K., Wasek, S., & Arbesman, M. (2012). Systematic review of the effect of home modification and fall prevention programs on falls and the performance of community-dwelling older adults. *American Journal of Occupational Therapy*, 66(3), 284–291.

⁸⁷ Patil, R., Uusi-Rasi, K., Tokola, K., Karinkanta, S., Kannus, P., & Sievanen, H. (2015). Effects of a Multimodal Exercise Program on Physical Function, Falls, and Injuries in Older Women: A 2-Year Community-Based, Randomized Controlled Trial. *Journal of the American Geriatrics Society*, 63(7), 1306–1313.

⁸⁸ Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed August 5, 2016.

⁸⁹ Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults—United States. *J Safety Res* 2016;58:99–103.

⁷³ Bohl, A.A., Phelan, E.A., Fishman, P.A., & Harris, J.R. (2012). How are the costs of care for medical falls distributed? The costs of medical falls by component of cost, timing, and injury severity. *The Gerontologist*, 52(5): 664–675.

⁷⁴ National Council on Aging (2015). Falls Prevention Fact Sheet. Retrieved from https://www.ncoa.org/wp-content/uploads/Fact-Sheet_Falls-Prevention.pdf.

⁷⁵ Avin G.K., Hanke A.T., Kirk-Sanche, N., McDonough M.C., Shubert E.T., Hardage, J., & Hartley, G. (2015). Management of Falls in Community-Dwelling Older Adults: Clinical Guidance Statement From the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. *Physical Therapy*, 95(6), 815–834. doi:10.2522/ptj.20140415.

⁷⁶ Hester, A.L. & Wei, F. (2013). Falls in the community: State of the science. *Clinical Interventions in Aging*, 8:675–679.

⁷⁷ Orces, C.H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. *Injury Prevention*, 20: 421–423.

⁷⁸ Liu, S.W., Obermeyer, Z., Chang, Y., & Shankar, K.N. (2015). Frequency of ED revisits and death among older adults after a fall. *American Journal of Emergency Medicine*, 33(8), 1012–1018. doi:10.1016/j.ajem.2015.04.023.

⁷⁹ Centers for Disease Control and Prevention (2015b). Important facts about falls. <http://www.cdc.gov/homeandrecreationsafety/falls/adultfalls.html>. Accessed April 19, 2016.

⁸⁰ Houry, D., Florence, C., Bladwin, G., Stevens, J., & McClure, R. (2015). The CDC Injury Center's response to the growing public health problem of falls among older adults. *American Journal of Lifestyle Medicine*, 10(1), 74–77.

fall with a serious injury.⁹⁰ Between 1988 and 2005, fractures accounted for 84 percent of hospitalizations for fall-related injuries among older adults.⁹¹ Researchers evaluated the cost of fall-related hospitalizations among older adults using the 2011 Texas Hospital Inpatient Discharge Data and determined that the average cost for fall-related hip fractures was \$61,715 for individuals 50 and older living in metropolitan areas and \$55,366 for those living nonmetropolitan areas.⁹²

To meet the IMPACT Act provision requiring the development of a standardized quality measure for the domain of Incidence of Major Falls (sections 1899B(c)(1)(D) of the Act), we proposed the standardized measure, The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We noted that this quality measure is NQF-endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011, demonstrating the measure is feasible, appropriate for assessing PAC quality of care, and could be used as a platform for standardized quality measure development. This quality measure is standardized across PAC settings and contains items that are collected uniformly in each setting's assessment instruments (that is, MDS, IRF-PAI, and LCDS). Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), revised in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291), and adopted to fulfill IMPACT Act requirements in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739). Data collection began in April 1, 2016 for LTCHs, and October 1, 2016 for SNFs and IRFs.

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

⁹⁰ Wu S, Keeler EB, Rubenstein LZ, Maglione MA, Shekelle PG. A cost-effectiveness analysis of a proposed national falls prevention program. *Clin Geriatr Med.* 2010;26(4): 751–66.

⁹¹ Orces, C.H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. *Injury Prevention*, 20: 421–423.

⁹² Towne, S.D., Ory, M.G., & Smith, M.L. (2014). Cost of fall-related hospitalizations among older adults: Environmental comparisons from the 2011 Texas hospital inpatient discharge data. *Population Health Management*, 17(6), 351–356.

c. Stakeholder Feedback

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting development. More information about this TEP can be found at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

In addition, we solicited public comment on this measure from September 19, 2016, through October 14, 2016. Overall, commenters were generally supportive of the measure, but raised concerns about the attribution given that home health clinicians are not present in the home at all times and recommended risk-adjusting the measure. The summary of this public comment period can be found at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

Finally, we presented this measure to the NQF-convened MAP on December 14, 2016. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the HH QRP as a cross-setting quality measure. The MAP highlighted the clinical significance of falls with major injury, while noting potential difficulties in collecting falls data and more limited action ability in the home health setting. The MAP suggested that CMS explore stratification of measure rates by referral origin when public reporting. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx. We solicited public comment on the stratification of the proposed measure, specifically on the measure rates for public reporting. The quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not

currently endorsed for the home health setting. We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We found one falls-related measure in home health titled, Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537).

We noted that we are also aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing "all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days."⁹³ After careful review, we determined that these measures are not appropriate to meet the IMPACT Act domain of incidence of major falls. Specifically—

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

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

d. Data Collection

For purposes of assessment data collection, we proposed to add two new falls-related items to the OASIS. The proposed falls with major injury item used to calculate the proposed quality measure does not duplicate existing items currently collected in the OASIS. We proposed to add two standardized items to the OASIS for collection at EOC, which comprises the Discharge from Agency, Death at Home, and Transfer to an Inpatient Facility time

⁹³ American Nurses Association (2014, April 9). Falls with injury. Retrieved from <http://www.qualityforum.org/QPS/0202>.

points: J1800 and J1900. The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since admission/resumption of care (prior assessment). If the answer to J1800 is yes, the next item (J1900) asks for the number of falls with: (a) No injury, (b) injury (except major), and (c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury). This measure would be calculated at the time of discharge (see 82 FR 35351). For technical information about this proposed measure, including information pertaining to measure calculation and the standardized patient assessment data element used to calculate this measure, we referred readers to the document titled, *Final Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

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

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

Comment: A few commenters supported the proposed measure, Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), noting that it aligned with measures in other post-acute care settings.

Response: We appreciate the commenters' support of the proposed measures.

Comment: Several commenters suggested that CMS further refine and test Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), to determine HHA setting applicability before adopting it for the HH QRP. Other commenters recommended that we provide training and time for HHAs to accommodate the new measures into their workflow. One commenter recommended that we review the impact of new measures on high needs beneficiaries.

Response: This measure is fully developed and testing of this measure is

based on a comprehensive field test of the items used to calculate this measure. Further, feedback from clinicians suggested that the items used to calculate this measure are feasible to collect in a Home health setting, reinforcing the measure testing by CMS and their measure contractor. Therefore, by way of testing results and consensus vetting, we believe that this measure is applicable to a home health setting.

With respect to training, we intend to engage in multiple activities including updating our manual and conducting training sessions, to ensure that HHAs understand how to properly report the measure.

Comment: A few commenters addressed the administrative burden of the measure, specifically focusing on the addition of items used in its calculation to the OASIS. Specifically, one of these commenters encouraged CMS to review the overall number of OASIS data elements and measures. The same commenter noted that HHAs already are evaluated on a falls measure, "Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate".

Response: This proposed measure is an outcome measure that we are adopting to satisfy the measure domain, Incidence of Major Falls, required by the IMPACT Act. The process measure, "Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate", is a measure that assesses falls risk rather than the outcome of a major fall. That measure is not aligned across post-acute care settings and therefore does not meet the requirements of the IMPACT Act.

Pertaining to the administrative burden, the proposed measure, "Falls with Major Injury," requires a total of two items to be added to the OASIS, which were considered feasible for collection in post-acute care settings. We believe these items add minimally to the quality reporting burden.

Comment: Several commenters noted that the home health setting is unique from facility-based care, making it difficult to assess or prevent patient falls. Commenters noted that home health staff are not with their patients around the clock, unlike facility-based care, and that patients may refuse or decline to follow staff recommendations on falls prevention.

Response: Assessing the incidence of major falls, which is associated with morbidity, mortality, and high costs, is required under the IMPACT Act and is also one of our major priorities for improving the quality of patient care. In order to ensure that this measure is appropriate for a home health setting,

we examined fall risk and prevalence among the cohort of home health patients by means of an analysis using 2015 OASIS data. In nearly 32 percent of the 5.3 million episodes with relevant data, the patient had a history of falls, defined as two or more falls, or any fall with an injury, in the previous 12 months. For the more than 6.1 million episodes where the patient received a multi-factor falls risk assessment using a standardized, validated assessment tool, the patient was found to have falls risk 93 percent of the time.

Additionally, there were nearly 100,000 instances documented where a patient required emergency care for an injury due to a fall. Our environmental scan identified evidence-based strategies that can and have been applied in the home health setting to reduce falls risk. Therefore, we believe that a measure of this type is important for both providers and individuals, to support person-centered care to properly assess for the risk of falling accompanied by a major injury to support proper care planning. In addition to meeting the requirements of the IMPACT Act, this measure will address the current gap in the HH QRP measure set for this type of injurious fall.

Comment: Several commenters recommended that this measure be risk-adjusted for the purpose of public-reporting, and that unadjusted rates be shared with providers via confidential feedback only. Commenters additionally suggested that there may be unintended consequences without risk adjustment such that HHAs may be hesitant to accept higher falls' risk patients for fear of the financial impact. The commenters stated that this may potentially limit the value of comparison amongst HHAs. According to one of these commenters, without risk adjustment, the measure could present a distorted correlation between the rate of major injuries related to falls and the quality of care provided by the agency. This will limit comparisons among home health agencies. Another commenter noted that stratifying results for public reporting may not be feasible given sample sizes and will not be a substitute for risk-adjustment.

Response: While we acknowledge that various patient characteristics can elevate the risk for falls, falls with major injury are considered to be 'never events. A never event is a serious reportable event. For that reason, we do not believe we should risk adjust the proposed measure. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. The need for risk assessment, based on varying

risk factors among residents, does not remove the obligation of providers to minimize that risk.

Comment: Many commenters noted that the falls measure is not endorsed by NQF for the home health setting and encouraged CMS to pursue NQF endorsement.

Response: While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an

important part of measure development and we plan to submit this measure for NQF endorsement consideration as soon as feasible.

Final Decision: After consideration of the comments received, we are finalizing as proposed the measure Percent of Residents Experiencing One or More Falls with Major Injury for adoption in the HH QRP beginning with the CY 2020 program year.

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

We solicited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 19 for use in future years in the HH QRP.

TABLE 19—HH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

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

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

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

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

Comment: Three commenters expressed general support for the

measures under consideration for future years. These commenters stated that measures should be tested in the home health setting prior to being finalized, highlighting that the home setting is different than other standardized institutional care settings and presents unique challenges to caregivers and beneficiaries. One of the commenters stated that the measurement domains are critically important in the home health setting and highly relevant, especially for patients whose goal is improvement, adding that the relevance, appropriateness, and applicability can only be discussed after validity and reliability testing is completed in the home health setting. Another commenter suggested leveraging changes in quality measures as an effort to safeguard the delivery of therapy services and ensure accountability on the part of the provider.

Response: We appreciate the recommendations and comments. We agree that all future measures should be adequately tested and found reliable for the home health setting.

Comment: Commenters supported the development of functional status measures. MedPAC also supported measures that cut-across sectors, as long as they are standardized, and noted they would support the self-care and mobility measure concepts for HHAs based on the IRF measure specifications, as long as CMS ensured that the measures are aligned across PAC settings. A few commenters recommended that functional measures may assess for beneficiaries who do not have the goal of improvement. Other commenters noted that stabilization measures are appropriate for quality improvement initiatives as they closely align with the goal of HH services to help patients maintain their current

level of function or when possible to improve it. Another commenter suggested closely monitoring functional status measures to determine the impact of other reforms, such as changes to the payment approaches, to determine the impact of these changes on patient outcomes.

Response: We appreciate the comments from MedPAC and others. We agree that the maintenance of function and avoidance or reduction in functional decline are appropriate goals for HH patients. We appreciate all recommendations and will take these comments into consideration as we consider measures for future rulemaking.

Comment: Three commenters specifically supported the potentially preventable within-stay hospitalization measure. MedPAC supported the development of a claims-based, potentially preventable hospitalization measure, adding that measuring potentially preventable hospitalizations holds providers accountable only for conditions that generally could have been managed by the HHA.

Response: We appreciate the comments from MedPAC and others pertaining to the potentially preventable within-stay hospitalization measure under consideration for future implementation in the HH QRP. We note that appropriately assessing hospital readmissions as an outcome is important, acknowledge the importance of avoiding unintended consequences that may arise from such assessments, and will take into consideration the commenters’ recommendations.

Comment: Commenters had suggestions for other measures that could be added to the HH QRP.

Response: We appreciate the commenters’ recommendations and will

take them into account in our future measure development work.

1. IMPACT Act Implementation Update

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

We did not receive any comments on this update.

H. Standardized Patient Assessment Data

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

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

In the CY 2018 HH PPS proposed rule (82 FR 35351) we proposed that the current pressure ulcer measure, Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), be replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The current pressure ulcer measure will remain in the HH QRP until that time. Accordingly, for the requirement that HHAs report standardized patient assessment data for the CY 2019 HH QRP, we proposed that the data elements used to calculate that measure meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(b)(v)(IV)(aa) of the Act for the beginning of the HH episode (for example, HH start of care/resumption of care), as well as the end of the HH episode (discharges) occurring during the first two quarters of CY 2018 will also satisfy the requirement to report standardized patient assessment data beginning with the CY 2019 HH QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important

for multiple reasons. Clinical decision making, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often avoidable.^{94 95 96 97 98 99} Pressure related wounds are considered healthcare acquired conditions.

As we noted, the data elements needed to calculate the current pressure ulcer measure are already included on the OASIS data set and reported by HHAs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.¹⁰⁰ The RAND pilot test of the MDS 3.0 data elements showed good reliability and are applicable to the OASIS because the data elements tested are the same as those used in the OASIS Data Set. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate “almost perfect” agreement using the Landis and Koch standard for strength of agreement.¹⁰¹

⁹⁴ Casey, G. (2013). “Pressure ulcers reflect quality of nursing care.” *Nurs N Z* 19(10): 20–24.

⁹⁵ Gorzoni, M.L. and S.L. Pires (2011). “Deaths in nursing homes.” *Rev Assoc Med Bras* 57(3): 327–331.

⁹⁶ Thomas, J.M., et al. (2013). “Systematic review: Health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.” *J Am Geriatr Soc* 61(6): 902–911.

⁹⁷ White-Chu, E.F., et al. (2011). “Pressure ulcers in long-term care.” *Clin Geriatr Med* 27(2): 241–258.

⁹⁸ Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med*. 2001;135 (8 Part 2), 744–51.

⁹⁹ Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.

¹⁰⁰ Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0*. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

¹⁰¹ Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159–174.

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the CY 2016 HH PPS (80 FR 68623). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (HHAs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs), is available at and <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Comment: Some commenters supported reporting the data elements already implemented in the HH QRP to fulfill the requirement to report standardized patient assessment data for the CY 2019 HH QRP. Specifically, the commenters supported the use of data elements used in calculation of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to fulfill this requirement. However, one commenter recommended that CMS implement such measures after public deliberation and discussion. A commenter suggested that CMS adopt the same policies in this CY 2018 HH PPS final rule as it adopted for IRFs, SNFs and LTCHs in the other final rules issued this year.

Response: We appreciate the support and where possible we have aligned with the other settings. We affirm that as we continue to implement measures, such as the pressure ulcer quality measure, we will continue to engage the public both during the measure development phase and through the rulemaking process.

Final Decision: After consideration of the public comments received, we are finalizing as proposed that the data elements currently reported by HHAs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), to meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act,

and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act beginning with the CY 2019 HH QRP.

2. Standardized Patient Assessment Data Reporting Beginning With the CY 2020 HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371), we described our proposals for the reporting of standardized patient assessment data by HHAs beginning with the CY 2020 HH QRP. LTCHs, IRFs, and SNFs are also required to report standardized patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). We proposed that HHAs will be required to report these data at admission (SOC/ROC) and discharge beginning on January 1, 2019, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision) that will be required at SOC/ROC only. Following the initial reporting year (which will be based on 6 months of data) for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on a full calendar year of such data reporting.

In selecting the data elements, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also noted that the patient and resident assessment instruments are considered part of the medical record and sought the inclusion of data elements relevant to patient care.

We also took into consideration the following factors for each data element: overall clinical relevance; ability to support clinical decisions, care planning, and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. In addition, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the

final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied.

We received several comments related to the reporting of the standardized patient assessment data.

Comment: Many commenters expressed significant concerns with respect to our standardized patient assessment data proposals. Several commenters stated that the new standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that we proposed to add to the OASIS. Several commenters noted that the addition of the proposed standardized patient assessment data elements will require hiring more staff, retraining staff on revised questions or coding guidance, and reconfiguring internal databases and EHRs. Other commenters expressed concerns about the gradual but significant past and future expansion of the OASIS through the addition of standardized patient assessment data elements and quality measures, noting the challenge of coping with ongoing additions and changes.

Several commenters expressed concern related to the implementation timeline in the proposed rule. Several commenters noted that CMS had not yet provided sufficient specifications or educational materials to support implementation of the new patient assessments in the proposed timeline. A few commenters urged CMS to delay the reporting of new standardized patient assessment data elements and to carefully assess whether all of the proposed standardized patient assessment data elements are necessary under the IMPACT Act.

Response: We understand the concerns raised by commenters that finalizing our standardized patient assessment data proposals will require HHAs to spend a significant amount of resources preparing to report the data, including updating relevant protocols and systems and training appropriate staff. We also recognize that we can meet our obligation to require the reporting of standardized patient assessment data for the categories described in section 1899B(b)(1)(B) of the Act while simultaneously being responsive to these concerns. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize the standardized patient assessment data elements we proposed for three of the five categories

under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

Although we believe that the proposed standardized patient assessment data elements would promote transparency around quality of care and price as we continue to explore reforms to the PAC payment system, the data elements that we proposed for each of these categories would have imposed a new reporting burden on HHAs. We agree that it would be useful to evaluate further how to best identify the standardized patient assessment data that would satisfy each of these categories; would be most appropriate for our intended purposes including payment and measure standardization; and can be reported by HHAs in the least burdensome manner. As part of this effort, we intend to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time HHAs have to prepare for the reporting of standardized patient assessment data in these categories. We intend to make new proposals for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act no later than in the CY 2020 HH PPS proposed rule.

In this final rule, we are finalizing the standardized patient assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. Unlike the standardized patient assessment data that we are not finalizing, the standardized patient assessment data that we proposed for Medical Conditions Co-Morbidities category is already required to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) quality measure, and the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure. We are finalizing the quality measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), and the additional standardized patient assessment data elements in Section GG to satisfy the category of Functional Status.

Comment: Some commenters expressed support for the adoption of standardized patient assessment data elements. Several of these commenters expressed support for standardizing the definitions as well as the implementation of the data collection effort. A few commenters also supported CMS' goal of standardizing the

questions and responses across all PAC settings. Another commenter approved of the efforts CMS is making to engage the PAC community on the implementation of the IMPACT Act, including holding Special Open Door Forums and Medicare Learning Network (MLN) Calls to communicate with providers about expectations/timelines over five years. MedPAC recognized the value of and need for a unified patient assessment system for PAC as part of a potential unified payment system for PAC.

Response: We appreciate the support.

Comment: A few commenters stated that there is insufficient evidence demonstrating the reliability and validity of the proposed standardized patient assessment data elements. Several commenters stated that the expanded standardized patient assessment data reporting requirements have not yet been adequately tested to ensure they collect accurate and useful data in the HHA setting.

Response: Our standardized patient assessment data elements were selected based on a rigorous multistage process described in the CY 2018 HH PPS proposed rule (82 FR 35344). In addition, we believe that the PAC PRD testing of many of these data elements provides good evidence from a large, national sample of patients and residents in PAC settings to support the use of these standardized patient assessment data elements in and across PAC settings. However, as previously explained, we have decided at this time not to finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Prior to making new proposals for these categories, we intend to conduct additional testing to ensure that the standardized patient assessment data elements we select are reliable, valid and appropriate for their intended use.

Comment: MedPAC suggested that CMS should be mindful that some data elements, when used for risk adjustment, may be susceptible to provider manipulation. MedPAC is concerned about the proposed elements such as oxygen therapy, intravenous medications, and nutritional approaches that may incentivize increased use of services. MedPAC supported the inclusion of these care items when they are tied to medical necessity, such as in previous MedPAC work, where patients were counted as using oxygen services only if they have diagnoses that typically require the use of oxygen. MedPAC encouraged CMS to take a

similar approach in measuring use of services that are especially discretionary. For some data elements, MedPAC suggested that CMS consider requiring a physician to attest that the reported service was reasonable and necessary and include a statement adjacent to the signature line warning that filing a false claim is subject to treble damages under the False Claims Act.

Response: We thank MedPAC for their support of the standardized patient assessment data elements that are associated with medical necessity. We appreciate their suggestions to mitigate the potential for false data submission and the unintended consequence of use of services that are not medically indicated.

Comment: While supporting the overall concept of standardization across PAC settings, several commenters strongly believed that the home health setting is different than institutional settings and urged CMS to consider this. One of these commenters encouraged CMS to perform testing specifically in the home health setting. Another commenter was concerned about the use of some data elements because they were not designed for the home health setting and require specialized training to accurately administer. Several commenters emphasized the importance of risk adjustment, with some stating that effective risk adjustment will be an essential policy feature for home health agencies to distinguish how patients and data collection in non-standardized settings such as the beneficiary's home differ from institutional settings.

Response: We acknowledge that the four PAC provider types each have unique challenges and provide unique services and appreciate the commenters' concerns specific to the home health setting and the potential variation in services and populations. Because of this, we conducted a thorough process of phased testing and stakeholder consensus to ensure we considered items that are aligned across PAC settings and are relevant to and feasible in each setting. However, for the reasons previously explained, we have decided at this time not to finalize the standardized patient assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act.

A full discussion of the standardized patient assessment data elements that we proposed to adopt for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act can be found in the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371). In light of our decision not to finalize our proposals

with respect to these categories, we are not going to address in this final rule the specific technical comments that we received on these proposed standardized patient assessment data elements. However, we appreciate the many technical comments we did receive specific to each of these data elements, and we will take them into consideration as we develop new proposals for these categories. In this section, we discuss the comments we received specific to the standardized patient assessment data we proposed to adopt and are finalizing in this final rule, for the categories of Functional Status and Medical Conditions and Co-Morbidities.

3. Standardized Patient Assessment Data by Category

a. Functional Status Data

We proposed that the data elements that will be reported by HHAs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), as described in section V.F.2 of the proposed rule will also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. Details on the data used to calculate this measure is discussed in section V.F.2. of this final rule.

To further satisfy the requirements under section 1899B(b)(1)(B)(i) of the Act and specifically our efforts to achieve standardized patient assessment data pertaining to functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider, we also proposed to adopt the functional status data elements that specifically address mobility and self-care as provided in the Act. We noted that these data elements were also used to calculate the function outcome measures implemented and/or proposed for implementation in three other post-acute quality reporting programs to which the IMPACT Act applies (Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients; Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients; Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients; and Application

of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients).

To achieve standardization, we noted that we have implemented such data elements, or sub-sets of the items, into the other post-acute care patient/resident assessment instruments and we proposed that they also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of such data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. These data elements currently are collected in the Section GG: Functional Abilities and Goals located in current versions of the MDS and the IRF-PAI assessment instruments.

As previously described, the patient assessment data that assess for functional status are from the CARE Item Set. They were specifically developed for cross-setting application and are the result of consensus building and public input. Further, we received public comment and input on these patient assessment data. Their reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. We referred the reader to section V.F.2 of the proposed rule for a full description of the CARE Item Set and description of the testing methodology and results that are available in several reports. For more information about this quality measure and the data elements used to calculate it, we referred readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), the FY 2016 IRF PPS final rule (80 FR 47100 through 47111), and the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

Therefore, we proposed to adopt the functional status data elements for the CY 2020 HH QRP, requiring HHAs to report these data starting on January 1, 2019. We noted that this proposal would align with the required reporting timeframe for the CY 2020 HH QRP. Following the initial 2 quarters of reporting for the CY 2020 HH QRP, we proposed that for subsequent years for the HH QRP, the reporting of standardized patient assessment data would be based on 12 months of data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

Comment: Several commenters, including MedPAC, supported the

collection of standardized patient assessment data across PAC settings. Some commenters specifically addressed support for CMS' proposal that data elements submitted to CMS to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631), would also satisfy the requirement to report standardized patient assessment data elements under section 1899B(b)(1)(B)(i) of the Act addressing functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.

Response: We appreciate the commenters' support.

Comment: A commenter suggested that CMS use the functional assessment item, GG0170C: Lying to sitting on the side of bed for purposes of standardization.

Response: We do not believe that collecting only GG170C would be sufficient for purposes of collecting standardized function data. We need a larger subset of Section GG items to calculate one of the measures that we are finalizing in this final rule, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), which is already finalized for SNFs, LTCHs and IRFs. Section GG in its entirety also meets the definition of standardized patient assessment data with respect to function because it is standardized across the four PAC settings. If we did not collect Section GG in its entirety from HHAs, we would be collecting a different set of function items from HHAs than we collect from other PAC provider types.

Final Decision: After consideration of the public comments received, we are finalizing that the data elements in Section GG: Functional Abilities and Goals meet the definition of standardized patient assessment data elements for functional status under section 1899B(b)(1)(B)(i) of the Act, specifically those Section GG standardized patient assessment data elements that are used in the quality measure, "Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)", and the additional standardized functional status data elements in Section GG. We note that Section GG includes item GG170Q, which we inadvertently omitted in the specifications that accompanied the CY

2018 HH PPS proposed rule. The Section GG data elements can be found in the Finalized Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements document available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQJQualityMeasures.html>. We are also finalizing that the data elements needed to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), meet the definition of standardized patient assessment data elements for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data elements under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

b. Medical Condition and Comorbidity Data

We proposed that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and that the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data element with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

"Medical conditions and co-morbidities" and the conditions addressed in the standardized assessment patient data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index (BMI), are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor outcomes, and can

result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care are a customary and best practice. Venous and arterial disease and diabetes are associated with insufficient low blood flow, which may increase the risk of tissue damage. These diseases commonly are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers due to shearing. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. These data elements are important for care planning, transitions in services and identifying medical complexities.

Comment: Commenters supported our proposal to use data elements already implemented in the HH QRP to satisfy the requirement to report standardized patient assessment data.

Response: We appreciate the support.

Final decision: After consideration of the public comments received, we are finalizing as proposed that the data elements currently reported by HHAs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the finalized measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

We note that for purposes of meeting the requirements of the CY 2020 HH QRP, HHAs will be required to report the data elements needed to calculate the current pressure ulcer measure for the last two quarters of CY 2018 (July–December) and the data elements needed to calculate the updated

pressure ulcer measure for the first two quarters of CY 2019 (January–June).

I. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Start Date for Reporting Standardized Patient Assessment Data by New HHAs

In the CY 2016 HH PPS final rule (80 FR 68703 through 68706), we adopted timing for new HHAs to begin reporting data on quality measures under the HH QRP. In the CY 2018 HH PPS proposed rule (82 FR 35371), we proposed that new HHAs would be required to begin reporting standardized patient assessment data on the same schedule.

Comment: One commenter supported our proposed policy to require that new HHAs begin reporting standardized patient assessment data on the same schedule that they are required to begin reporting data on quality measures.

Response: We thank the commenter for the support.

Final Decision: After consideration of the comments we received, we are finalizing our proposal that new HHAs will be required to begin reporting standardized patient assessment data on the same schedule that they are currently required to begin reporting other quality data under the HH QRP.

2. Mechanism for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Under our current policy, HHAs report data by completing applicable sections of the OASIS, and submitting the OASIS to CMS through the QIES, ASAP system. For more information on HH QRP reporting through the QIES ASAP system, we referred readers to <https://www.qtso.com/index.php>. In addition to the data currently submitted on quality measures as previously finalized and described in Table 18 of this rule, in the CY 2018 HH PPS proposed rule (82 FR 35372), we proposed that HHAs would be required to begin submitting the proposed standardized patient assessment data for HHA Medicare and Medicaid quality episodes that begin or end on or after January 1, 2019 using the OASIS.

Further, we proposed that all standardized patient assessment data elements would be collected at SOC/ROC using the OASIS item set, and all except the Brief Interview for Mental Status (BIMS), Hearing, and Vision data elements are or would be collected at discharge using the OASIS item set. Details on the modifications and assessment collection for the OASIS for the proposed standardized data are available at <https://www.cms.gov/>

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

We invited public comment on these proposals.

Comment: We received a comment in support of the proposed mechanisms for reporting standardized patient assessment in the same manner as the quality measure data for assessment based data beginning with the CY 2019 HH QRP.

Response: We thank the commenter for its support.

Final Decision: After consideration of the public comment received, we are finalizing our policy as proposed to use the same data reporting mechanism for the submission of the standardized patient assessment data elements that is already used for reporting quality measure data used in the HH QRP beginning with the CY 2019 HH QRP.

3. Schedule for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35372) we proposed to apply our current schedule for the reporting of measure data to the reporting of standardized patient assessment data, beginning with the CY 2019 HH QRP. Under that policy, except for the first program year for which a measure is adopted, HHAs must report data on measures for HHA Medicare and Medicaid quality episodes that occur during the 12-month period (between July 1 and June 30) that applies to the program year. For the first program year for which a measure is adopted, HHAs are only required to report data on HHA Medicare and Medicaid quality episodes that begin on or after January 1 and end up to and including June 30 of the calendar year that applies to that program year. For example, for the CY 2019 HH QRP, data on measures adopted for earlier program years must be reported for all HHA Medicare and Medicaid quality episodes that begin on or after July 1, 2017, and end on or before June 30, 2018. However, data on new measures adopted for the first time for the CY 2019 HH QRP program year must only be reported for HHA Medicare and Medicaid quality episodes that begin or end during the first two quarters of CY 2018. Tables 20 and 21 illustrate this policy and its proposed application to the reporting of standardized patient assessment data, using CY 2019 and CY 2020 as examples.

TABLE 20—SUMMARY ILLUSTRATION OF INITIAL REPORTING FOR NEWLY ADOPTED MEASURES AND PROPOSED STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY Q1 AND Q2 DATA FOR THE HH QRP *

| Proposed data collection/submission reporting period * | Proposed data submission deadlines beginning with CY 2019 HH QRP * |
|--|--|
| January 1, 2018–June 30, 2018. | July 31, 2018. |

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.
 – The term “CY 2019 HH QRP” means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

TABLE 21—SUMMARY ILLUSTRATION OF OASIS 12 MONTH DATA REPORTING FOR MEASURES AND PROPOSED STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE HH QRP *

| Proposed data collection/submission reporting period * | Proposed data submission deadlines beginning with CY 2020 HH QRP * ^ |
|--|--|
| July 1, 2018–June 30, 2019. | July 31, 2019. |

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.
 ^ The term “CY 2020 HH QRP” means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

We invited comment on our proposal to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

We did not receive any comments regarding this proposal.

Final Decision: We are finalizing our proposal as proposed to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

4. Schedule for Reporting Quality Measures Beginning With the CY 2020 HH QRP

As discussed in section V.I. of this final rule, we are finalizing the adoption of three quality measures beginning with the CY 2020 HH QRP: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; Application of The Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674); and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). In the CY 2018 HH PPS proposed rule (82 FR 35372), we proposed that HHAs would report data on these measures using OASIS reporting that is submitted through the QIES ASAP system. More information on OASIS reporting using the QIES ASAP system is located at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html>.

For the CY 2020 HH QRP, under our current policy HHAs will be required to report these data for HHA Medicare and Medicaid quality episodes that begin or end during the period from January 1, 2019, to June 30, 2019. Beginning with the CY 2021 HH QRP, we proposed that HHAs would be required to submit data for the entire 12-month period from July 1 to June 30. Further, for the purposes of measure calculation, our policy was established in the CY 2017 HH PPS final rule (81 FR76784) that data are utilized using calendar year timeframes with review and correction periods.

Comment: A commenter supported the proposed schedule for reporting the three new quality measures beginning with the CY 2020 QRP. However, the commenter also suggested that there is a disparity in how home health providers are reimbursed, which creates challenges for their submission of the required data.

Response: We interpret the comment to be suggesting that Medicare reimbursement rates for HH services, compared to Medicare rates for post-acute care services furnished by different provider-types, may affect the ability of HHAs to comply with the data reporting requirements under the HH QRP. We are cognizant of the challenges of data collection and we consider this when developing and adopting our measures.

Final Decision: After consideration of the public comment received, we are finalizing our policy as proposed for the Schedule for Reporting the Quality Measures beginning with the CY 2020 HH QRP.

5. Input Sought for Data Reporting Related to Assessment Based Measures

We have received input suggesting that we expand the population for quality measurement to include all patients regardless of payer. Approximately 75 percent of home health expenditures in 2014 were made by either Medicare or Medicaid and currently both Medicare and Medicaid collect and report data for OASIS. We believe that expanding the patient population for which OASIS collects data will allow us to ensure data that is representative of quality provided to all patients in the HHA setting, and therefore, allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also appreciate that collecting quality data on all patients regardless of payer source may create additional burden. However, we have also received input that the effort to separate out Medicare and Medicaid beneficiaries, who are currently reported through OASIS, from other patients, creates clinical and work flow implications with an associated burden too, and noted that we further appreciate that it is common practice for HHAs to collect OASIS data on all patients, regardless of payer source. Thus, we sought input on whether we should require quality data reporting on all HH patients, regardless of payer, where feasible—noting that because Medicare Part A claims data are submitted only with respect to Medicare beneficiaries, claims-based measures would continue to be calculated only for Medicare beneficiaries. We would like to clarify that CMS sought comment on this all payor topic and therefore there

is no proposed policy to finalize. We appreciate the comments received and will take all recommendations into consideration.

Comment: Several commenters supported data collection on all patients regardless of payor. One commenter requested that CMS provide additional explanation of what the benefit would be to collecting OASIS data on all patients regardless of payor. Several commenters stated that the addition of OASIS reporting for all patients regardless of payor will impose significant burden on HHAs. Some commenters noted that they used separate assessment documents for patients who are insured by private payors and that they used these assessments, in part, to avoid the burden of OASIS. A few commenters suggested that the collection of OASIS data on all patients regardless of payor could result in healthcare professionals spending more time with documentation and less time providing patient care. Some commenters suggested that if CMS requires HHAs to submit OASIS assessments on all patients, they might need to increase their staff hours, hire additional staff and incur additional expenses.

Response: We continue to believe that the reporting of all-payor data under the HH QRP would add value to the program and provide a more accurate representation of the quality provided by HHAs. Although we acknowledge the concerns raised by commenters regarding the potential burden of reporting all-payer data and on the potential impact of such a requirement for the HH QRP, we wish to clarify that under the HH Conditions of Participation (42 CFR 484.55), each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must also incorporate the use of the current version of the OASIS items, using the language and groupings of the OASIS items, as specified by the Secretary.

Comment: We received several comments pertaining to the submission requirements of the OASIS instrument. Some commenters suggested that OASIS data was required for submission on only Medicare fee-for-service beneficiaries, while other commenters stated that HHAs must complete the OASIS for all Medicare and Medicaid patients. Another commenter noted that the HH Conditions of Participation

already apply to all patients in a Medicare-certified HHA. Other commenters stated that they did not know what patient populations must be given an OASIS assessment.

Response: As previously discussed, for the purposes HH QRP, data reporting on the OASIS includes all Medicare and Medicaid beneficiaries. However, the comprehensive assessment must also incorporate the collection of the current version of the OASIS items, using the language and groupings of the OASIS items.

Comment: Several commenters stated concerns about the potential impact of all-payor information on the HH QRP public reporting and on the HHVBP model because private payors differ from CMS with regard to care pathways, approval, and authorization processes. Some commenters stated that private payors had proprietary information and that CMS would exceed its authority if it required all-payor reporting. Commenters also stated that some private insurers had different requirements than CMS pertaining to the number of visits paid for by such insurers, which would inhibit the agency in comparing performance across HHAs.

Response: We acknowledge concerns raised for the HHVBP model and the potential downstream impacts. With regard to the commenter suggesting that private payors' patients would generate proprietary information, we want to clarify that the OASIS is not a proprietary instrument and therefore we do not believe that a requirement that HHAs use the OASIS in compliance with our CoPs raises proprietary issues.

J. Other Provisions for the CY 2019 HH QRP and Subsequent Years

1. Application of the HH QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2016 HH PPS final rule (80 FR 68703 through 68704), we defined the pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a SOC or ROC assessment and a matching End of Care EOC assessment. EOC assessments comprise the Discharge from Agency, Death at Home and Transfer to an

Inpatient Facility time points. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the "Quality Assessments Only" (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705).

Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS final rule. We finalized a policy through which HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015, to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016, to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017, to June 30, 2018). An HHA that does not meet this requirement for a calendar year will be subject to a two percentage point reduction to the market basket percentage increase that will otherwise apply for that calendar year. In the CY 2018 HH PPS proposed rule (82 FR 35373), we proposed to apply the threshold requirements established in the CY 2016 HH PPS rule to the submission of standardized patient assessment data beginning with the CY 2019 HH QRP.

Comment: Commenter provided feedback on the QAO standard which requires that at least 90 percent of OASIS assessments be usable for calculating quality measures or be subject to a 2-percentage point reduction to the market basket update for CY 2019. One commenter agreed with our proposal to apply the HH QRP data completion thresholds to the submission of standardized patient assessment data beginning in the CY 2019 HH QRP. A commenter suggested that the proposed 90 percent threshold is very high and may be difficult for small or rural providers meet, and suggested changing this to 80 percent or higher.

Response: We disagree that the 90 percent threshold for CY 2019 is too high or difficult for HHAs to meet. The home health CoPs as codified (42 CFR 484.55) mandate use of the OASIS data set. OASIS reporting was first implemented on July 19, 1999 and in 2007, we adopted mandatory OASIS reporting for quality reporting purposes under section 1895(b)(3)(B)(v)(I) of the Act. Furthermore, HHAs have been required to submit OASIS data as a condition of payment of their Medicare claims since 2010. Since, HHAs have been required to report OASIS data for

the last 18 years as a CoP in the Medicare program and as a condition of payment of their Medicare claims for the past 7 years, our establishment of a 90 percent threshold for OASIS reporting should not place any new or additional burden on HHAs.

Final Decision: After consideration of the comments received, we are finalizing our proposal as proposed to extend our current HH QRP data completion requirements to the submission of standardized patient assessment data.

2. HH QRP Submission Exception and Extension Requirements

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances outside their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. In the CY 2018 HH QRP proposed rule (82 FR 35373), we proposed to define a “disaster” as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an HHA may have the ability to conduct a full patient assessment and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the agency’s data files to be destroyed, but it could hinder the HHA’s ability to meet the QRP’s data submission deadlines. In this scenario, the HHA will potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, an HHA may not have had the ability to conduct a full patient assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the agency may not have complete data to submit to CMS.

We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize HHAs in these circumstances or to unduly increase their burden during these times. Therefore, we proposed a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters, beginning with the CY 2019 HH QRP, when there are certain extraordinary circumstances outside the control of the HHA. When an exception or extension is granted, we would not reduce the HHA’s PPS payment for failure to comply with the requirements of the HH QRP.

We proposed that if an HHA seeks to request an exception or extension for the HH QRP, the HHA must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The HHA may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the HHA Exception and Extension mailbox at HHAPureConsiderations@cms.hhs.gov. Requests sent to CMS through any other channel would not be considered as valid requests for an exception or extension from the HH QRP’s reporting requirements for any payment determination.

The subject of the email must read “HH QRP Exception or Extension Request” and the email must contain the all following information:

- HHA CCN.
- HHA name.
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).
- HHA’s reason for requesting an exception or extension.
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles.
- A date when the HHA believes it will be able to again submit HH QRP data and a justification for the proposed date.

We proposed that exception and extension requests would need to be signed by the HHA’s CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual would be able to submit such a request on behalf of the HHA. Following receipt of the email, we would provide a: (1) Written acknowledgement, using the contact information provided in the

email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) a formal response to the CEO or any CEO-designated HHA personnel, using the contact information provided in the email, indicating our decision.

We stated that this proposal would not preclude us from granting exceptions or extensions to HHAs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we were to make the determination to grant an exception or extension to all HHAs in a region or locale, we proposed to communicate this decision through routine communication channels to HHAs and vendors, including, but not limited to, issuing memos, emails, and notices on our HH QRP Web site once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We also proposed that we may grant an exception or extension to HHAs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the HHA to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If an HHA is granted an exception, we would not require that the HHA submit any measure data for the period of time specified in the exception request decision. If we grant an extension to the original submission deadline, the HHA would still remain responsible for submitting quality data collected during the timeframe in question, although we would specify a revised deadline by which the HHA must submit this quality data.

We also proposed that any exception or extension requests submitted for purposes of the HH QRP would apply to that program only, and not to any other program we administer for HHAs such as survey and certification. OASIS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs 1-5, 1-6, 1-7, 1-8 at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf>.

We intend to provide additional information pertaining to exceptions and extensions for the HH QRP, including any additional guidance, on

the HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

In the CY 2018 HH PPS proposed rule (82 FR 35374), we proposed to codify the HH QRP Submission Exception and Extension Requirements at § 484.250(d) of our regulations.

Comment: One commenter expressed support for the creation of an exception and extension request process for HHAs that experience disasters or other extraordinary circumstances.

Response: We thank the commenter for the comment and support.

Final Decision: After consideration of comments received, we are finalizing the adoption of the policy as proposed for HH QRP Submission Exception and Extension Requirements beginning with the CY 2019 HH QRP and our decision to codify the HH QRP Submission Exception and Extension Requirements at § 484.250(d) of our regulations.

3. HH QRP Submission Reconsideration and Appeals Procedures

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096). At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be noncompliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2 percentage point reduction to its market basket percentage update for that calendar year.

Similar to our other quality reporting programs, such as the SNF QRP, the LTCH QRP, and the IRF QRP, we include an opportunity for the providers to request a reconsideration of our initial noncompliance determination. To be consistent with other established quality reporting programs and to provide an opportunity for HHAs to seek reconsideration of our initial noncompliance decision, in the CY 2018 HH PPS proposed rule (82 FR 35374 through 35375) we proposed a process that enables an HHA to request reconsideration of our initial noncompliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the HH QRP reporting requirements for a particular calendar year.

For the CY 2019 HH QRP, and subsequent years, we proposed a HHA would receive a notification of

noncompliance if we determine that the HHA did not submit data in accordance with the HH QRP reporting requirements for the applicable CY. The purpose of this notification is to put the HHA on notice that the HHA: (1) Has been identified as being non-compliant with the HH QRP's reporting requirements for the applicable calendar year; (2) will be scheduled to receive a reduction in the amount of two percentage points to its market basket percentage update for the applicable calendar year; (3) may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

We stated that we would only consider requests for reconsideration after an HHA has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle or from the Medicare Administrative Contractors assigned to process the provider's claims. To obtain the compliance reports, we stated that HHAs must access the CASPER Reporting Application. HHAs can access the CASPER Reporting application via their CMS OASIS System Welcome page by selecting the CASPER Reporting link. The "CASPER Reports" link will connect an HHA to the QIES National System Login page for CASPER Reporting.

We proposed to disseminate communications regarding the availability of compliance reports through routine channels to HHAs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our HH QRP Web site once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We proposed that an HHA would have 30 days from the date of the letter

of noncompliance to submit to us a request for reconsideration. This proposed time frame would allow us to balance our desire to ensure that HHAs have the opportunity to request reconsideration with our need to complete the process and provide HHAs with our reconsideration decision in a timely manner. We proposed that an HHA may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may grant a request by an HHA to extend the proposed deadline for reconsideration requests. We stated that it would be the responsibility of an HHA to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also proposed that as part of the HHA's request for reconsideration, the HHA would be required to submit all supporting documentation and evidence demonstrating full compliance with all HH QRP reporting requirements for the applicable calendar year, that the HHA has requested an extension or exception for which a decision has not yet been made, that the HHA has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section V.I.2. of this final rule, but failed to file a timely request of exception. We proposed that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

We proposed that the documentation and evidence may include copies of any communications that demonstrate the HHA's compliance with the HH QRP, as well as any other records that support the HHA's rationale for seeking reconsideration, but must not include any protected health information (PHI). We stated that we intended to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for HHAs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We proposed that an HHA wishing to request a reconsideration of our initial noncompliance determination would be required to do so by submitting an email to the following email address: HHAPureConsiderations@cms.hhs.gov.

Any request for reconsideration submitted to us by an HHA would be required to follow the guidelines outlined on our HH QRP Web site once it is available once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

All emails must contain a subject line that reads "HH QRP Reconsideration Request." Electronic email submission is the only form of reconsideration request submission that will be accepted by us. We proposed that any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, would not be considered as a valid reconsideration request.

We proposed that a reconsideration request include the all of the following information:

- HHA CMS Certification Number (CCN).

- HHA Business Name.
- HHA Business Address.
- The CEO contact information including name, email address, telephone number, and physical mailing address; or the CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address.

- CMS identified reason(s) for noncompliance from the non-compliance notification.
- The reason(s) for requesting reconsideration.

We proposed that the request for reconsideration must be accompanied by supporting documentation demonstrating compliance. Following receipt of a request for reconsideration, we would provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email would be sent to the HHA CEO or CEO designated representative, using the contact information provided in the reconsideration request, notifying the HHA of our decision.

We also proposed that the notifications of our decision regarding reconsideration requests may be made available through a traceable delivery method, such as certified U.S. mail or registered U.S. mail or through the use of CASPER reports. If the HHA is dissatisfied with the decision rendered at the reconsideration level, the HHA

may appeal the decision to the PRRB under 42 CFR 405.1835. We believe the proposed process is more efficient and less costly for CMS and for HHAs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

In the CY 2018 HH PPS proposed rule (82 FR 35375), we proposed to add the HH QRP Submission Reconsideration and Appeals Procedures at §§ 484.250(e) and (f) of our regulations.

Comment: One commenter expressed support for the submission reconsideration and appeals procedures for HHAs.

Response: We thank the commenter for the comment and support.

Final Decision: After consideration of the public comments received, we are finalizing as proposed the adoption of the policy for HH QRP Submission Reconsideration and Appeals Procedures for the CY 2019 HH QRP and subsequent years, which will be codified at § 484.250(e) and (f) of our regulations.

K. Policies Regarding Public Display of Quality Measure Data for the HH QRP

Our home health regulations, at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Section 1899B(g) of the Act requires that data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified "application date". In addition, section 1895(b)(3)(B)(v)(III) of the Act requires the Secretary to establish procedures for making data submitted under section 1895(b)(3)(B)(v)(II) of the Act available to the public, and section 1899B(g)(1) of the Act requires the Secretary to do the same with respect to HHA performance on measures specified under sections 1899B(c)(1) and (d)(1) of the Act. Section 1895(b)(3)(B)(v)(III) of the Act requires that the public reporting procedures for data submitted under subclause (II) ensure that a HHA has the

opportunity to review the data that is to be made public with respect to it prior to such data being made public. Under section 1899B(g)(2) of the Act, the public reporting procedures for performance on measures under sections 1899B(c)(1) and (d)(1) of the Act must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, (which refers to public display and review requirements in the Hospital Inpatient Quality Reporting (Hospital IQR) Program), that a HHA has the opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies must be constructed from data collected in a standardized and uniform manner.

In the CY 2017 HH PPS final rule (81 FR 76785 through 76786), we finalized procedures that allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public. Information on how to review and correct data on IMPACT Act measures that are to be made public before those measure data are made public can be found on the HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html>. We did not propose any changes to these policies in the CY 2018 HH PPS proposed rule.

However, in the CY 2018 HH PPS proposed rule (82 FR 35375 and 35376), pending the availability of data, we proposed to publicly report data beginning in CY 2019 for the following two assessment-based measures: (1) Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. Data collection for these two assessment-based measures began on OASIS on January 1, 2017. We proposed to publicly report data beginning in CY 2019 for these assessment-based measures based on four rolling quarters of data, beginning with data collected for discharges in 2017.

We proposed to publicly report data beginning in CY 2019 for the following

3 claims-based measures: (1) Medicare Spending Per Beneficiary—PAC HH QRP; (2) Discharge to Community—PAC HH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. As adopted in the CY 2017 HH PPS final rule (81 FR 43773), for the MSPB—PAC HH QRP measure, we will use 1 year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH

QRP. For the Discharge to Community—PAC HH QRP measure we will use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, we will use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY

2015, 2016 and 2017 claims data for public reporting.

Finally, we proposed to assign HHAs with fewer than 20 eligible cases during a performance period to a separate category: “The number of patient episodes for this measure is too small to report,”¹⁰² to ensure the statistical reliability of the measures. If a HHA had fewer than 20 eligible cases, the HHA’s performance would not be publicly reported for the measure for that performance period.

TABLE 22—NEW HH QRP MEASURES PROPOSED FOR CY 2019 PUBLIC DISPLAY

Proposed measures:

Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678).
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP.
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.
Discharge to Community—(PAC) HH QRP.
Medicare Spending Per Beneficiary (PAC) HH QRP.

We invited public comments on these proposals for the public display of quality data.

Comment: Commenters provide feedback regarding the public display of quality measures beginning CY 2019 for data collected beginning CY 2017. One commenter questioned if the Medicare Spending Per Beneficiary—PAC HH QRP measure includes spending data that is specific to HH services or the total amount of Medicare spending for beneficiaries specific to a defined timeframe. One commenter did not support public reporting for the Discharge to Community—PAC HH QRP measure based on the potential for providers to have incentives against the appropriate use of hospice services in a patient-centered continuum of care. Another commenter did not support publicly reporting the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP measure, stating that this measure is dependent on physician response and is not a measure of HHA quality or performance. Finally, a commenter suggested a dashboard of measures aligned across home health quality initiatives, including star ratings, Home Health Compare and the HH VBP demonstration.

Response: We appreciate the commenters’ suggestions regarding the public display of quality measures. As finalized in the CY 2017 rule, the MSPB—PAC HH QRP measure episode is comprised of a treatment period and an associated services period. 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. More detailed specifications for the MSPB—PAC HH QRP measure, including the MSPB—PAC HH QRP measure, are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

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. We wish to also 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 that bypass hospice care. With respect to the public reporting of Drug Regimen Review Conducted with Follow-Up for Identified Issues, the intent of the measure is to capture timely follow up for all potential clinically significant issues. We believe the timely review and follow up of potentially 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, and that this measure helps to ensure that high quality care services are furnished and that patient harm is avoided.

With regard to the commenter’s suggestion that we provide a dashboard that communicates alignment across the measures, we will take the commenter’s suggestion under consideration.

Comment: We received several comments about the Quality of Patient Care star ratings. One commenter noted increased administrative and clinical costs HHAs incur to maintain or improve the number of stars instead of focusing on improving the scores on individual quality measures. Another commenter stated that poor performing home health agencies could rate higher than their actual performance while good or excellent agencies could rate lower than their actual performance due to the way the data is calculated.

Response: We thank the commenters, but note that these comments relate to issues for which we made no proposals in the CY 2018 HH proposed rule. Therefore, we believe these comments to be outside the scope of the proposed rule and will not address them here.

Final Decision: After considering the comments received, we are finalizing our proposals regarding public display of quality measure data in the HH QRP.

L. Mechanism for Providing Confidential Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care (PAC) providers on their performance on the measures specified under subsections (c)(1) and (d)(1) of section 1899B of the Act, beginning one year after the specified application date that applies to such measures and PAC

¹⁰² This language is currently available as Footnote #4 on Home Health Compare (<https://>

www.medicare.gov/HomeHealthCompare/Data/Footnotes.html).

providers. In the CY 2017 HH PPS final rule (81 FR 76702), we finalized processes to allow HH providers the opportunity to review their data and information using confidential feedback reports that will enable HHAs to review their performance on the measures required under the HH QRP.

Information on how to obtain these and other reports available to the HH QRP can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html>. We did not propose any changes to this policy.

M. Home Health Care CAHPS® Survey (HHCAPHS)

In the CY 2017 HH PPS final rule (81 FR 76787), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAPHS) Survey for the Home Health Quality Reporting Program and along with OASIS measures, HHCAPHS participation is required for the Annual Payment Update (APU). In the CY 2017 HH PPS final rule, we finalized the reporting requirements and the data submission dates for the CY 2017–CY 2020 APU periods. We proposed to continue the HHCAPHS requirements in future years for the continuous monthly data collection and quarterly data submission of HHCAPHS data.

1. Background and Description of HHCAPHS

The HHCAPHS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. For more details about the HHCAPHS Survey please see 81 FR 76787 through 76788.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAPHS survey vendor. This requirement continues, and Medicare-certified agencies are required to provide a monthly list of their HHCAPHS-eligible patients to their respective HHCAPHS survey vendors. Home health agencies are not allowed to influence their patients about how the HHCAPHS survey.

As previously required, new HHCAPHS survey vendors are required to attend Introduction training, and current HHCAPHS vendors are required to attend Update training conducted by CMS and the HHCAPHS Survey Coordination Team. New HHCAPHS vendors need to pass a post-training certification test. We have

approximately 25 approved HHCAPHS survey vendors. The list of approved HHCAPHS survey vendors is available at <https://homehealthcahps.org>.

2. HHCAPHS Oversight Activities

We stated in prior final rules that all approved HHCAPHS survey vendors are required to participate in HHCAPHS oversight activities to ensure compliance with HHCAPHS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAPHS survey vendors follow the HHCAPHS Protocols and Guidelines Manual.

In the CY 2013 HH PPS final rule (77 FR 67095 through 67097, 67164), we codified at § 484.250(c)(3) that all approved HHCAPHS survey vendors are required to fully comply with all HHCAPHS oversight activities.

In the CY 2018 HH PPS proposed rule (82 FR 35377), we restated the HHCAPHS requirements for CY 2019, because participation occurs in the period of the publication of the proposed and final rules for CY 2018. We additionally presented the HHCAPHS requirements for CY 2020 for the sake of continuity. We proposed the HHCAPHS requirements for the CY 2021 Annual Payment Update.

3. HHCAPHS Requirements for the CY 2019 HH QRP

In the CY 2017 HH PPS final rule (81 FR 76789), we finalized the requirements for the CY 2019 HH QRP. For the CY 2019 HH QRP, we require continuous monthly HHCAPHS data collection and reporting for four quarters. The data collection period for the CY 2018 HH QRP includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAPHS data files to the HHCAPHS Data Center for the second quarter 2017 by 11:59 p.m., eastern daylight time (e.d.t.) on October 19, 2017; for the third quarter 2017 by 11:59 p.m., eastern standard time (e.s.t.) on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For more details on the CY 2019 HH QRP, we refer readers to 81 FR 76789.

4. HHCAPHS Requirements for the CY 2020 HH QRP

In the CY 2017 HH PPS final rule (81 FR 76789), we finalized the requirements for the CY 2020 HH QRP. For the CY 2020 HH QRP, we require continued monthly HHCAPHS data

collection and reporting for four quarters. The data collection period for the CY 2020 HH QRP includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAPHS data files to the HHCAPHS Data Center for the second quarter 2018 by 11:59 p.m., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 18, 2019. These deadlines are firm; no exceptions will be permitted.

For more details about the CY 2020 HH QRP, we refer readers to 81 FR 76789.

5. HHCAPHS Requirements for the CY 2021 HH QRP

For the CY 2021 HH QRP, we proposed to require the continued monthly HHCAPHS data collection and reporting for four quarters. The data collection period for the CY 2021 HH QRP includes the second quarter 2019 through the first quarter 2020 (the months of April 2019 through March 2020). HHAs will be required to submit their HHCAPHS data files to the HHCAPHS Data Center for the second quarter 2019 by 11:59 p.m., e.d.t. on October 17, 2019; for the third quarter 2019 by 11:59 p.m., e.s.t. on January 16, 2020; for the fourth quarter 2019 by 11:59 p.m., e.d.t. on April 16, 2020; and for the first quarter 2020 by 11:59 p.m., e.d.t. on July 16, 2020. These deadlines are firm; no exceptions will be permitted.

For the CY 2021 HH QRP, we proposed to require that all HHAs with fewer than 60 HHCAPHS-eligible unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are exempt from the HHCAPHS data collection and submission requirements for the CY 2021 HH QRP, upon completion of the CY 2021 HHCAPHS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAPHS-eligible, unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 were proposed to be required to submit their patient counts on the CY 2021 HHCAPHS Participation Exemption Request form posted on <https://homehealthcahps.org> from April 1, 2019 to 11:59 p.m., e.d.t. to March 31, 2020. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAPHS.

We proposed to automatically exempt HHAs receiving Medicare certification on or after the start of the period in which HHAs do their patient count for a particular year's HHCAPHS data submission from the HHCAPHS reporting requirement for the year. We proposed that HHAs receiving Medicare-certification on or after April 1, 2019 would be exempt from the HHCAPHS reporting requirement for the CY 2021 HH QRP. As we have finalized in previous years, we proposed that these newly-certified HHAs do not need to complete the HHCAPHS Participation Exemption Request Form for the CY 2021 HH QRP.

6. HHCAPHS Reconsiderations and Appeals Process

As finalized in previous rules, we proposed that HHAs must monitor their respective HHCAPHS survey vendors to ensure that vendors submit their HHCAPHS data on time, by accessing their HHCAPHS 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 HHCAPHS Data Center.

We proposed to continue HHCAPHS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 67068, 67164), we codified the current guideline that all approved HHCAPHS survey vendors must fully comply with all HHCAPHS oversight activities. We included this survey requirement at § 484.250(c)(3).

For further information on the HH QRP reconsiderations and appeals process, please see section V.J.3. of this final rule.

7. Summary

We did not propose any changes to the participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey (HHCAPHS). We only proposed updates to the information to reflect the dates for future HH QRP years. We encouraged HHAs to keep up-to-date about the HHCAPHS by regularly viewing the official Web site for the HHCAPHS at <https://homehealthcahps.org>. We noted that HHAs can also send an email to the HHCAPHS Survey Coordination Team at hcahps@rti.org or to CMS at homehealthcahps@cms.hhs.gov, or telephone toll-free (1-866-354-0985) for more information about the HHCAPHS Survey.

Final Decision: We did not receive any comments on our proposals. Accordingly, we are finalizing the proposals. We again strongly encourage HHAs to keep up-to-date about the HHCAPHS by regularly viewing the official Web site for the HHCAPHS at <https://homehealthcahps.org>. HHAs can also send an email to the HHCAPHS Survey Coordination Team at hcahps@rti.org or to CMS at homehealthcahps@cms.hhs.gov, or telephone toll-free (1-866-354-0985) for more information about the HHCAPHS Survey.

VI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. We note that we

will submit a revised information collection request (OMB control number 0938-1279) to OMB for review. This will also extend the information collection request which expires December 30, 2019. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

This final rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for the HH QRP

We believe that the burden associated with the HH QRP is the time and effort associated with data collection and reporting. As of April 1, 2017, there are approximately 12,149 HHAs reporting quality data to CMS. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 23.

TABLE 23—U.S. BUREAU OF LABOR STATISTICS' MAY 2016 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

| Occupation title | Occupation code | Mean hourly wage (\$/hr) | Fringe benefit (100%) (\$/hr) | Adjusted hourly wage (\$/hr) |
|--|-----------------|--------------------------|-------------------------------|------------------------------|
| Registered Nurse (RN) | 29-1141 | \$34.70 | \$34.70 | \$69.40 |
| Physical therapists HHAs | 29-1123 | 46.42 | 46.42 | 92.84 |
| Speech-Language Pathologists (SLP) | 29-1127 | 37.60 | 37.60 | 75.20 |
| Occupational Therapists (OT) | 29-1122 | 40.25 | 40.25 | 80.50 |

The OASIS changes that we are finalizing in section V.D of this final rule will result in the removal of 70 data elements from the OASIS at the time point of Start of Care (SOC), 70 data elements at the time point of Resumption of Care (ROC), 18 data

elements at the time point of Follow-up (FU), 42 data elements at the time point of Transfer to an Inpatient Facility (TOC), 1 data element at the time point of Death at Home (Death), and 34 data elements at the time point of Discharge from Agency (Discharge). These data

items will not be used in the calculation of quality measures adopted in the HH QRP, or for other purposes that are not related to the HH QRP.

Section V.F.1. of this final rule adopts a new pressure ulcer measure to replace the current pressure ulcer measure that

we previously specified under section 1899B(c)(1)(B) of the Act, beginning with the CY 2020 HH QRP. The replacement measure is entitled, “Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.” The new measure will be calculated using data elements that are currently collected and reported using the OASIS–C2 (version effective January 1, 2017). Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure will result in the removal of item M1313, which has 6 data elements that cover the same issues that are addressed in the pressure ulcer assessment that will be required under the new pressure ulcer measure, making it duplicative and no longer necessary to separately collect.

In sections V.F.2. of this final rule, we are adopting a new quality measure under section 1899B(c)(1)(A) of the Act beginning with the CY 2020 HH QRP entitled “Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).” In the CY 2018 HH PPS proposed rule (82 FR 35379), we stated that if we finalized the adoption of this measure, we would add 13 standardized patient assessment data elements at SOC, 13 data elements at ROC, 15 standardized patient assessment data elements at FU, and 13 standardized patient assessment data elements at Discharge. We inadvertently did not include in our original burden estimate two OASIS items (GG0170Q and GG0170RR) that are needed to calculate this measure.¹⁰³ We have updated our burden estimate to include these items, and note that as a result of finalizing this measure, we will be adding 15 standardized patient assessment data elements at SOC, 15 standardized patient assessment data elements at ROC, 16 standardized patient assessment data elements at FU, and 15 standardized patient assessment data elements at Discharge.

In sections V.F.3. of this final rule, we are adopting a new quality measure under section 1899B(c)(1)(D) of the Act

beginning with the CY 2020 HH QRP entitled “Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF# 0674).” The new measure will be calculated using new standardized data elements added to the OASIS. Specifically, we are adding 4 data elements at TOC, 4 data elements at Death, and 4 data elements at Discharge.

In sections V.H.2 and V.H.3 of this final rule, we are finalizing our proposal to collect standardized patient assessment data with respect to the Medical Condition and Comorbidity category beginning with the CY 2019 HH QRP and Functional Status beginning with the CY 2020 HH QRP. As a result, we are adding to the OASIS the standardized patient assessment data elements associated with these categories, which include 17 standardized patient assessment data elements at SOC, 17 standardized patient assessment data elements at ROC, and 12 standardized patient assessment data elements at Discharge.

We are not finalizing our proposals to require HHAs to report standardized patient assessment data elements for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. As a result, we will not be adding to the OASIS the data elements associated with these proposals, which included 36 data elements at SOC, 36 data elements at ROC, or 24 data elements at discharge.

The OASIS instrument is used for both the HH QRP and the HH PPS. In sections III.E. of this final rule, after receiving detailed comments from the public we are not finalizing the implementation of the HHGM. Therefore, we are not finalizing the proposal to add two current OASIS–C2 items, M1033 and M1800, at the FU time point or to remove collection of eight current OASIS–C2 integumentary status items at the FU time point.

In summary, as a net result of the policies we are finalizing in this final rule, we will be removing 38 data

elements at SOC, 38 data elements at ROC, 2 data elements at FU, 38 data elements at TOC and 9 data elements at Discharge. We will be adding 3 data elements at Death.

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to section 1899B, or to the sections of the OASIS that require modification to achieve the standardization of patient assessment data. We are, however, setting out the burden as a courtesy to advise interested parties of the actions’ time and costs and for reference in the regulatory impact analysis (RIA) section VII. of this final rule. The requirement and burden will be submitted to OMB for review and approval when the modifications to the OASIS have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, there is a reduction in clinician burden per OASIS assessment of 11.4 minutes at SOC, 11.4 minutes at ROC, 0.6 minutes at FU, 11.4 minutes at TOC 2.7 minutes at Discharge. There is an increase in clinician burden per assessment of 0.9 minutes at Death.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of \$72.40, inclusive of fringe benefits, using the hourly wage data in Table 23. Individual providers determine the staffing resources necessary.

Table 24 shows the total number of assessments submitted in CY 2016 and estimated burden at each time point.

TABLE 24—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

| Time point | CY 2016 assessments completed | Estimated burden (\$) |
|---|-------------------------------|-----------------------|
| Start of Care | 6,261,934 | – \$86,139,164.10 |
| Resumption of Care | 1,049,247 | – 14,443,441.73 |
| Follow-up | 3,797,410 | – 2,749,324.84 |
| Transfer to an inpatient facility | 1,892,099 | – 26,027,713.84 |
| Death at Home | 41,128 | 44,665.01 |
| Discharge from agency | 5,120,124 | – 16,681,363.99 |

TABLE 24—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT—Continued

| Time point | CY 2016 assessments completed | Estimated burden (\$) |
|-------------|-------------------------------|-----------------------|
| Total | 18,161,942 | – 145,986,343.50 |

* Estimated Burden (\$) at each Time-Point = (# CY 2016 Assessments Completed) x (clinician burden [min]/60) x (\$72.40 [weighted clinician average hourly wage]).

Based on the data in Table 24, for the 12,149 active Medicare-certified HHAs in April 2017, we estimate the total average decrease in cost associated with changes to the HH QRP at \$12,016.33 per HHA annually, or \$145,986,343.50 for all HHAs annually. This corresponds to an estimated reduction in clinician burden associated with changes to the HH QRP of 166 hours per HHA annually, or 2,016,386 hours for all HHAs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1279.

C. Submission of PRA-Related Comments

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

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

1. Access CMS’ Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786–1326.

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

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 home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the

prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

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

The HHVBP Model will apply a payment adjustment based on an HHA’s performance on quality measures to test the effects on quality and expenditures.

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). We included a detailed alternatives considered section in the CY 2018 HH PPS proposed rule, which outlined alternatives considered for the CY 2018 HH PPS payment update, the proposed HHGM, and HH VBP model (82 FR 35388 and 35389).

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 savings impacts related to the HHVBP Model as a whole are estimated at a total projected 5-year gross savings of \$378 million assuming a savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions; the portion attributable to this final rule is negligible. In section VII. of this final rule, we identified a reduction in our regulatory reporting burden of \$ 145,986,343.50. We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this final rule will not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately \$148 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$148 million or more.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year’s proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters

reviewed this year’s rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of commenters will be a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/2016/may/naics4_621100.htm). Assuming an average reading speed, we estimate that it will take approximately 2.6 hours for the staff to review half of this final rule. For each HHA that reviews the rule, the estimated cost is \$273.42 (2.6 hours x \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$368,023.32 (\$273.42 x 1,346 reviewers).

1. HH PPS for CY 2018

The update set forth in this final rule applies to Medicare payments under HH PPS in CY 2018. Accordingly, the following analysis describes the impact in CY 2018 only. We estimate that the net impact of the policies in this final rule is approximately \$80 million in decreased payments to HHAs in CY 2018. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.C.3. of this final rule. Therefore, the estimated impact of the 2018 wage index and the recalibration of the case-mix weights for 2018 is zero. The –\$80 million impact reflects the distributional effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision (\$100 million decrease), a 1 percent home health payment update percentage (\$190 million increase), and a –0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of –0.9 percent (\$170 million decrease). The \$80 million in decreased payments is reflected in the last column of the first row in Table 25 as a 0.4 percent decrease in expenditures when comparing CY 2017 payments to estimated CY 2018 payments.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact

on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA.

Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs’ visits are Medicare-paid visits, and therefore, the majority of HHAs’ revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this final rule will result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS rule will have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 25, by HHA type and location.

With regards to options for regulatory relief, the sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to authorize rural add-on payments past December 31, 2017. We believe it is appropriate to reduce the national, standardized 60-day episode payment amount by 0.97 percent in CY 2018 to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction

of approximately \$378 million (81 FR 76795). We do not believe the changes finalized in this final rule will affect the prior estimates.

C. Detailed Economic Analysis

This final rule updates for CY 2018 the HH PPS rates contained in the CY 2017 HH PPS final rule (81 FR 76702 through 76797). The impact analysis of this final rule presents the estimated expenditure effects of policy changes that are to be finalized. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2016. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care

Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

1. HH PPS for CY 2018

Table 25 represents how HHA revenues are likely to be affected by the policy changes in this final rule for CY 2018. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2016. The first column of Table 25 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2018 wage index. The fourth column shows the payment effects of the CY 2018 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the payment effects from the sunset of the

rural add-on payment provision in statute. The seventh column shows the effects of the CY 2018 home health payment update percentage.

The last column shows the combined effects of all the policies in this final rule. Overall, it is projected that aggregate payments in CY 2018 will decrease by 0.4 percent. As illustrated in Table 25, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2018 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2018 relative to CY 2017, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization. In addition, we clarify that there are negative estimated impacts attributed to the sunset of the rural add-on provision for HHAs located in urban areas as well as rural areas. This is due to the fact that HHAs located in urban areas provide services to patients located in rural areas and payments are based on the location of the beneficiary.

TABLE 25—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018

| | Number of agencies | CY 2018 wage index ¹ % | CY 2018 case-mix weights ² % | 60-Day episode rate nominal case-mix reduction ³ % | Sunset of rural add-on | HH payment update percentage ⁴ % | Total % |
|---|--------------------|--------------------------------------|--|--|------------------------|--|---------|
| All Agencies | 11,056 | 0.0 | 0.0 | -0.9 | -0.5 | 1.0 | -0.4 |
| Facility Type and Control | | | | | | | |
| Free-Standing/Other Vol/NP | 1,110 | 0.0 | 0.1 | -0.8 | -0.4 | 1.0 | -0.1 |
| Free-Standing/Other Proprietary | 8,724 | 0.0 | 0.0 | -0.9 | -0.4 | 1.0 | -0.3 |
| Free-Standing/Other Government | 318 | -0.3 | 0.1 | -0.9 | -1.3 | 1.0 | -1.4 |
| Facility-Based Vol/NP | 634 | 0.0 | 0.2 | -0.8 | -0.7 | 1.0 | -0.3 |
| Facility-Based Proprietary | 81 | -0.3 | 0.2 | -0.9 | -1.3 | 1.0 | -1.3 |
| Facility-Based Government | 189 | 0.0 | 0.2 | -0.9 | -1.5 | 1.0 | -1.2 |
| Subtotal: Freestanding | 10,152 | 0.0 | 0.0 | -0.9 | -0.4 | 1.0 | -0.3 |
| Subtotal: Facility-based | 904 | 0.0 | 0.2 | -0.8 | -0.8 | 1.0 | -0.4 |
| Subtotal: Vol/NP | 1,744 | 0.0 | 0.1 | -0.8 | -0.5 | 1.0 | -0.2 |
| Subtotal: Proprietary | 8,805 | 0.0 | 0.0 | -0.9 | -0.5 | 1.0 | -0.4 |
| Subtotal: Government | 507 | -0.2 | 0.2 | -0.9 | -1.4 | 1.0 | -1.3 |
| Facility Type and Control: Rural | | | | | | | |
| Free-Standing/Other Vol/NP | 265 | 0.2 | 0.1 | -0.9 | -2.5 | 1.0 | -2.1 |
| Free-Standing/Other Proprietary | 832 | -0.1 | -0.2 | -0.9 | -2.3 | 1.0 | -2.5 |
| Free-Standing/Other Government | 224 | -0.4 | 0.0 | -0.9 | -2.6 | 1.0 | -2.9 |
| Facility-Based Vol/NP | 285 | -0.4 | 0.1 | -0.8 | -2.7 | 1.0 | -2.8 |
| Facility-Based Proprietary | 42 | -0.1 | 0.1 | -0.9 | -2.7 | 1.0 | -2.6 |
| Facility-Based Government | 142 | -0.2 | 0.1 | -0.8 | -2.6 | 1.0 | -2.5 |
| Facility Type and Control: Urban | | | | | | | |
| Free-Standing/Other Vol/NP | 845 | -0.9 | 0.1 | -0.8 | -0.1 | 1.0 | -0.7 |
| Free-Standing/Other Proprietary | 7,892 | 0.0 | 0.0 | -0.9 | -0.2 | 1.0 | -0.1 |
| Free-Standing/Other Government | 94 | -0.3 | 0.2 | -0.9 | -0.1 | 1.0 | -0.1 |
| Facility-Based Vol/NP | 349 | 0.1 | 0.2 | -0.8 | -0.1 | 1.0 | 0.4 |
| Facility-Based Proprietary | 39 | -0.5 | 0.2 | -0.9 | -0.2 | 1.0 | -0.4 |

TABLE 25—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018—Continued

| | Number of agencies | CY 2018 wage index ¹ % | CY 2018 case-mix weights ² % | 60-Day episode rate nominal case-mix reduction ³ % | Sunset of rural add-on | HH payment update percentage ⁴ % | Total % |
|---|--------------------|-----------------------------------|---|---|------------------------|---|---------|
| Facility-Based Government | 47 | 0.3 | 0.2 | -0.9 | -0.3 | 1.0 | 0.3 |
| Facility Location: Urban or Rural | | | | | | | |
| Rural | 1,790 | -0.1 | -0.1 | -0.9 | -2.4 | 1.0 | -2.5 |
| Urban | 9,266 | 0.0 | 0.0 | -0.9 | -0.2 | 1.0 | -0.1 |
| Facility Location: Region of the Country (Census Region) | | | | | | | |
| New England | 359 | 0.0 | 0.1 | -0.8 | -0.3 | 1.0 | 0.0 |
| Mid Atlantic | 495 | 0.0 | -0.1 | -0.8 | -0.2 | 1.0 | -0.1 |
| East North Central | 2,235 | 0.0 | 0.2 | -0.9 | -0.4 | 1.0 | -0.1 |
| West North Central | 711 | 0.2 | 0.1 | -0.9 | -0.8 | 1.0 | -0.4 |
| South Atlantic | 1,736 | -0.2 | -0.1 | -0.9 | -0.3 | 1.0 | -0.5 |
| East South Central | 426 | -0.2 | -0.2 | -0.9 | -1.3 | 1.0 | -1.6 |
| West South Central | 2,987 | 0.2 | -0.3 | -0.9 | -0.7 | 1.0 | -0.7 |
| Mountain | 683 | -0.2 | 0.1 | -0.9 | -0.4 | 1.0 | -0.4 |
| Pacific | 1,377 | 0.1 | 0.5 | -0.9 | -0.1 | 1.0 | 0.6 |
| Other | 47 | 0.1 | -1.0 | -0.8 | -0.6 | 1.0 | -1.3 |
| Facility Size (Number of 1st Episodes) | | | | | | | |
| <100 episodes | 3,092 | 0.0 | 0.1 | -0.9 | -0.4 | 1.0 | -0.2 |
| 100 to 249 | 2,467 | 0.1 | 0.2 | -0.9 | -0.5 | 1.0 | -0.1 |
| 250 to 499 | 2,225 | 0.1 | 0.2 | -0.9 | -0.5 | 1.0 | -0.1 |
| 500 to 999 | 1,710 | 0.0 | 0.0 | -0.9 | -0.5 | 1.0 | -0.4 |
| 1,000 or More | 1,562 | -0.1 | -0.1 | -0.9 | -0.5 | 1.0 | -0.6 |

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

¹ The impact of the CY 2018 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this final rule.

² The impact of the CY 2018 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this final rule.

³ The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2018 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

⁴ The CY 2018 home health payment update percentage reflects the home health payment update of 1 percent as described in section III.C.1 of this 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.

The following is a summary of the public comments received on the “Regulatory Impact Analysis” and our responses:

Comment: A commenter requested that CMS provide the impact analyses of the case-mix weight changes that are annually proposed.

Response: The analyses of the annual case-mix weight changes are included in Table 25 in the fourth column titled, “CY 2018 Case-Mix Weights”.

Comment: A commenter stated that when isolating the case mix changes from CY2017 to the CY2018 proposed rule, they are seeing an average impact of -0.58% which differs from the CMS projected 0.0 percent in Table 54 of the proposed rule. This analysis is for the case-mix components only (weights and budget neutrality factor), and excludes all other components such as wage index, nominal CM reduction, sunset of rural add-on, and the payment update percentage. The commenter requested

an explanation of the apparent discrepancy.

Response: We estimate that all HHAs nationwide will see a decrease in average case-mix between CY 2017 and CY 2018 of 1.6 percent due to recalibration of the case-mix weights (hence the BN factor of 1.6 percent). In increasing the base rate by 1.6 percent to offset the decrease in average case-mix, those HHAs that have a decrease in average case-mix of less than 1.6 percent between CY 2017 and CY 2018 will see a small increase in payment for CY 2018 due to the case-mix weights budget neutrality factor. Those HHAs that have a decrease in average case-mix of more than 1.6 percent due to the case-mix weight recalibration between CY 2017 and CY 2018 will see a small decrease in payment for CY 2018 (generally proportional to the decrease in average case-mix above and beyond -1.6 percent). The adjustment for case-mix normalization is budget neutral in the

aggregate but not so for individual HHAs.

2. HHVBP Model

Table 26 displays our analysis of the distribution for 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 CY 2015 baseline data and CY 2016 PY 1 data for OASIS-based measures, claims-based hospitalization and Emergency Department (ED) measures, and HHCAHPS data. The estimated impacts account for the minimum 40 HHCAHPS completed surveys policy, beginning with PY 1, as finalized in this rule. For PY 1 and 2, we show the impacts based on ten OASIS quality measures (9 OASIS quality measures were used for PY 3 through 5 to represent the removal of the Drug Education measure), two claims-based measures in QIES, five HHCAHPS measures, and the three new measures

(using the October 2016 and January 2017 submission data), using the QIES Roll Up File data in the same manner as they will be in the Model. HHAs were classified as being in the smaller or larger volume cohort using the 2015 Quality Episode File, as updated for this final rule, which is created using OASIS assessments. The basis of the payment adjustment was derived from complete 2015 claims data. We note that this impact analysis is based on the aggregate value of all nine states.

Table 27 displays our analysis of the distribution of possible payment adjustments based on the same CY 2015 baseline data and 2016 PY 1 data used to calculate Table 26, providing information on the estimated impact of the finalized policies in this final rule. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. This analysis reflects that only HHAs that have data for at least five measures that meet the requirements of § 484.305, as amended by this final rule, will be included in the LEF and will have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated 1,600 plus HHAs in the selected states that will compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in section IV.B. of the CY 2017 HH PPS final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs do not have a separate smaller-volume cohort and thus there will only

be one cohort that will include all the HHAs in that state. As indicated in Table 27, Arizona, Maryland, North Carolina, Tennessee and Washington will only have one cohort while Florida, Iowa, Massachusetts, and Nebraska will have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 26 HHAs exempt from the requirement that their beneficiaries complete HHCAPHS surveys because they provided HHA services to fewer than 60 beneficiaries in CY 2015. Therefore, 26 HHAs competed in Iowa's smaller-volume cohort for the 2016 performance year under the Model.

Using CY 2015 baseline year data and CY 2016 PY 1 data and the maximum payment adjustment for PY 1 of 3-percent (as applied in CY 2018), based on the ten OASIS quality measures, two claims-based measures in QIES, the five HHCAPHS measures, and the three new measures, the smaller-volume HHAs in Iowa have a mean payment adjustment of -0.1 percent (Table 27). Ten percent of HHAs in the smaller-volume cohort will be subject to payment adjustments of more than minus 1.1 percent (-1.1 percent), the lowest 10th percentile. The next columns provide the distribution of scores by percentile; we see that the cohort payment adjustment distribution for HHAs in Iowa in the smaller-volume cohort ranges from -1.1 percent at the 10th percentile to +1.5 percent at the 90th percentile, while the cohort payment adjustment distribution median is -0.3 percent.

Table 28 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's

beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have better performance.

The payment adjustment percentages are calculated at the state and size cohort level. Hence, the values of each separate analysis in the tables reflect the baseline year of 2015 and the performance year of 2016. There are 1,622 Medicare-certified HHAs in the nine selected states that have a sufficient number of measures to receive a payment adjustment in the Model. We note in Table 28, that at the time of our analysis, seven of the 1,622 Medicare-certified HHAs were missing information needed for the stratifications in the table. Not all Medicare-certified HHAs in the nine states have a payment adjustment because some HHAs are servicing too small of a population to report an adequate number of measures to calculate a TPS. However, as noted previously, our updated analysis found that the number of such HHAs was not affected by the proposed minimum 40 HHCAPHS survey policy, which we are finalizing.

Additional analysis (see Table 29) was conducted to illustrate the effect of the finalized policy to require 40 or more completed HHCAPHS surveys versus 20 or more completed HHCAPHS surveys. We include information on average statewide TPS by size of the HHA. The percentage difference in the average TPS across all larger-volume HHAs for each state ranges from -0.3 percent through 1.8 percent and the majority of states are close to zero.

TABLE 26—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 | 2.8 | -1.3 | -0.9 | -0.6 | -0.4 | -0.1 | 0.2 | 0.5 | 0.8 | 1.4 |
| 5% Payment Adjustment For Performance Year 2 of the Model | 4.6 | -2.2 | -1.6 | -1.0 | -0.6 | -0.1 | 0.3 | 0.8 | 1.4 | 2.4 |
| 6% Payment Adjustment For Performance Year 3 of the Model** .. | 5.8 | -2.8 | -1.9 | -1.3 | -0.7 | -0.2 | 0.4 | 1.0 | 1.7 | 3.0 |
| 7% Payment Adjustment For Performance Year 4 of the Model** .. | 6.7 | -3.2 | -2.2 | -1.5 | -0.9 | -0.2 | 0.5 | 1.2 | 1.9 | 3.5 |
| 8% Payment Adjustment For Performance Year 5 of the Model** .. | 7.7 | -3.7 | -2.5 | -1.7 | -1.0 | -0.2 | 0.5 | 1.4 | 2.2 | 4.0 |

* Based on measure performance data from Performance Year 1 (January 1, 2016 to December 31, 2016), the baseline year (January 1, 2015 to December 31, 2015), and home health Medicare claims data from 2015.
** For Performance Years 3, 4, and 5, the payment adjustment rate simulation incorporated the removal of the Drug Education measure.

TABLE 27—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
[Based on a 3-percent payment adjustment]

| State | Number of HHAs | Average payment adj. % | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% |
|---|----------------|------------------------|------|------|------|------|------|-----|-----|-----|-----|
| HHA Cohort in States with no small cohorts (percent) | | | | | | | | | | | |
| AZ | 114 | -0.1 | -1.3 | -0.9 | -0.7 | -0.4 | -0.2 | 0.1 | 0.5 | 0.7 | 1.1 |
| MD | 51 | 0.1 | -0.8 | -0.8 | -0.6 | -0.4 | 0.1 | 0.4 | 0.5 | 0.8 | 1.0 |

TABLE 27—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT—Continued
[Based on a 3-percent payment adjustment]

| State | Number of HHAs | Average payment adj. % | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% |
|--|----------------|------------------------|------|------|------|------|------|------|-----|-----|-----|
| NC | 163 | -0.1 | -1.3 | -0.9 | -0.5 | -0.2 | 0.0 | 0.2 | 0.4 | 0.7 | 0.9 |
| TN | 123 | -0.1 | -1.3 | -1.0 | -0.7 | -0.4 | -0.1 | 0.2 | 0.3 | 0.6 | 1.0 |
| WA | 57 | -0.1 | -1.0 | -0.8 | -0.6 | -0.2 | -0.2 | 0.0 | 0.3 | 0.3 | 0.8 |
| Smaller-volume HHA Cohort in states with small cohort (percent) | | | | | | | | | | | |
| FL | 82 | 0.1 | -1.6 | -1.3 | -1.0 | -0.6 | -0.2 | 0.6 | 0.9 | 1.5 | 2.2 |
| IA | 26 | -0.1 | -1.1 | -1.0 | -0.9 | -0.6 | -0.3 | 0.0 | 0.4 | 0.8 | 1.5 |
| MA | 16 | -0.4 | -1.7 | -1.5 | -1.5 | -1.1 | -0.8 | -0.4 | 0.3 | 0.8 | 2.3 |
| NE | 16 | 0.2 | -1.6 | -1.5 | -1.0 | -0.1 | 0.2 | 0.6 | 1.1 | 1.2 | 2.7 |
| Large-volume HHA Cohort in states with small cohort (percent) | | | | | | | | | | | |
| FL | 706 | 0.1 | -1.2 | -0.8 | -0.5 | -0.3 | 0.0 | 0.2 | 0.6 | 1.0 | 1.7 |
| IA | 99 | -0.2 | -1.4 | -1.1 | -0.8 | -0.5 | -0.3 | 0.0 | 0.3 | 0.7 | 1.2 |
| MA | 124 | -0.2 | -1.5 | -1.1 | -0.8 | -0.6 | -0.3 | 0.0 | 0.3 | 0.6 | 1.1 |
| NE | 45 | 0.0 | -1.4 | -0.7 | -0.6 | -0.2 | 0.1 | 0.3 | 0.7 | 0.9 | 1.2 |

Notes: Based on measure performance data from Performance Year 1 (January 1, 2016 to December 31, 2016), the baseline year (January 1, 2015 to December 31, 2015), and home health Medicare claims data from 2015.

TABLE 28—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS
[Based on a 3-percent payment adjustment]¹

| Cohort | Number of HHAs | Average payment adj. % | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% |
|---|----------------|------------------------|------|------|------|------|------|------|-----|-----|-----|
| Small HHA (<60 patients in CY 2015) | 150 | 0.0 | -1.6 | -1.4 | -1.0 | -0.6 | -0.3 | 0.2 | 0.7 | 1.2 | 2.2 |
| Large HHA (≥60 patients in CY 2015) | 1,465 | 0.0 | -1.2 | -0.9 | -0.6 | -0.3 | -0.1 | 0.2 | 0.5 | 0.8 | 1.4 |
| Low % Dually-Eligible | 403 | 0.1 | -1.1 | -0.8 | -0.5 | -0.2 | 0.1 | 0.3 | 0.6 | 0.9 | 1.4 |
| Medium % Dually-Eligible | 809 | -0.1 | -1.3 | -0.9 | -0.6 | -0.4 | -0.1 | 0.1 | 0.4 | 0.6 | 1.0 |
| High % Dually-Eligible | 403 | 0.1 | -1.5 | -1.1 | -0.8 | -0.5 | -0.1 | 0.3 | 0.7 | 1.3 | 2.1 |
| Low Acuity | 403 | -0.3 | -1.6 | -1.2 | -1.0 | -0.7 | -0.4 | -0.1 | 0.2 | 0.6 | 1.1 |
| Mid Acuity | 809 | 0.0 | -1.2 | -0.9 | -0.6 | -0.4 | -0.1 | 0.1 | 0.4 | 0.7 | 1.2 |
| High Acuity | 403 | 0.4 | -1.1 | -0.6 | -0.3 | 0.0 | 0.3 | 0.6 | 0.9 | 1.4 | 2.1 |
| All non-rural beneficiaries | 956 | 0.1 | -1.3 | -0.9 | -0.6 | -0.3 | 0.0 | 0.3 | 0.6 | 1.0 | 1.7 |
| Up to 35% rural beneficiaries | 384 | -0.1 | -1.3 | -0.9 | -0.6 | -0.3 | -0.1 | 0.1 | 0.4 | 0.7 | 1.0 |
| Over 35% rural beneficiaries | 275 | -0.1 | -1.3 | -1.0 | -0.7 | -0.4 | -0.2 | 0.0 | 0.2 | 0.7 | 1.2 |
| Non-Profit HHAs | 295 | 0.1 | -1.1 | -0.8 | -0.5 | -0.2 | 0.0 | 0.3 | 0.6 | 0.9 | 1.3 |
| For-Profit HHAs | 1,211 | 0.0 | -1.4 | -1.0 | -0.6 | -0.4 | -0.1 | 0.2 | 0.5 | 0.8 | 1.5 |
| Government HHAs | 109 | -0.2 | -1.1 | -0.9 | -0.8 | -0.5 | -0.3 | 0.0 | 0.1 | 0.4 | 1.0 |
| Freestanding | 1,460 | 0.0 | -1.3 | -0.9 | -0.6 | -0.4 | -0.1 | 0.2 | 0.5 | 0.8 | 1.5 |
| Facility-based | 155 | -0.1 | -1.3 | -0.9 | -0.6 | -0.3 | -0.1 | 0.1 | 0.3 | 0.7 | 1.0 |

Notes: ¹Rural beneficiaries identified based on the CBSA code reported on the claim. Acuity is based on the average case-mix weight for non-LUPA episodes. Low acuity is defined as the bottom 25 percent (among HHVBP Model participants); mid-acuity is the middle 50 percent and high acuity is the highest 25 percent. Note that at the time of the analysis, seven HHAs were missing information needed for the stratifications in this table.

TABLE 29—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE*

| State | HHA count | Average TPS | | | | Minimum payment adjustment | | Maximum payment adjustment | |
|----------------------------|-----------|-------------|------------|------------|--------------|----------------------------|----------------|----------------------------|----------------|
| | | 20 Minimum | 40 Minimum | Difference | % Difference | 20 Minimum (%) | 40 Minimum (%) | 20 Minimum (%) | 40 Minimum (%) |
| Larger-volume HHAS | | | | | | | | | |
| AZ | 107 | 42.160 | 42.924 | 0.765 | 1.8 | -2.3 | -2.3 | 2.8 | 2.7 |
| FL | 706 | 39.110 | 39.731 | 0.621 | 1.6 | -2.5 | -2.5 | 3.0 | 3.0 |
| IA | 99 | 43.191 | 43.186 | -0.005 | 0.0 | -2.1 | -2.1 | 2.0 | 2.4 |
| MA | 124 | 41.380 | 41.256 | -0.125 | -0.3 | -2.6 | -2.5 | 2.4 | 2.5 |
| MD | 50 | 49.179 | 49.549 | 0.370 | 0.7 | -1.3 | -1.3 | 2.0 | 2.0 |
| NC | 163 | 45.798 | 46.187 | 0.390 | 0.8 | -2.1 | -2.1 | 2.9 | 2.9 |
| NE | 45 | 42.252 | 43.028 | 0.776 | 1.8 | -2.1 | -2.1 | 2.6 | 2.4 |
| TN | 119 | 47.462 | 47.540 | 0.078 | 0.2 | -2.5 | -2.3 | 1.6 | 2.1 |
| WA | 57 | 51.840 | 51.712 | -0.128 | -0.2 | -1.5 | -1.6 | 1.1 | 1.1 |
| Total | 1,470 | | | | | | | | |
| Smaller-volume HHAS | | | | | | | | | |
| AZ | 7 | 36.706 | 36.706 | 0.000 | 0.0 | -1.8 | -1.9 | 1.0 | 1.0 |
| FL | 82 | 42.810 | 42.810 | 0.000 | 0.0 | -2.3 | -2.3 | 2.9 | 2.9 |
| IA | 26 | 38.663 | 38.663 | 0.000 | 0.0 | -1.8 | -1.8 | 2.2 | 2.2 |
| MA | 16 | 25.004 | 25.004 | 0.000 | 0.0 | -1.7 | -1.7 | 2.3 | 2.3 |

TABLE 29—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE*—Continued

| State | HHA count | Average TPS | | | | Minimum payment adjustment | | Maximum payment adjustment | |
|-------------|-----------|-------------|------------|------------|--------------|----------------------------|----------------|----------------------------|----------------|
| | | 20 Minimum | 40 Minimum | Difference | % Difference | 20 Minimum (%) | 40 Minimum (%) | 20 Minimum (%) | 40 Minimum (%) |
| | | | | | | | | | |
| MD | 1 | 61.135 | 61.135 | 0.000 | 0.0 | 0.8 | 0.8 | 0.8 | 0.8 |
| NE | 16 | 37.485 | 37.485 | 0.000 | 0.0 | -2.6 | -2.6 | 3.0 | 3.0 |
| TN | 4 | 39.983 | 39.983 | 0.000 | 0.0 | -1.8 | -1.8 | 1.9 | 1.9 |
| Total | 152 | | | | | | | | |
| Total | 1,622 | | | | | | | | |

*OASIS, claims and HHCAHPS measures run from January 1, 2016 to December 31, 2016 for Performance Year 1. The baseline year is January 1, 2015 to December 31, 2015. Payment based on 2015 Medicare home health claims data. North Carolina and Washington did not have any smaller-volume HHAs.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any HHA that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 1,206, or approximately 9.9 percent, of the 12,149 active Medicare-certified HHAs, did not receive the full annual percentage increase for CY 2017 because they did not meet the requirements of the HH QRP. Information is not available to determine the precise number of HHAs that will not meet the requirements to receive the full annual percentage increase for the CY 2018 payment determination.

As noted in section VII.B. of this final rule, the net effect of our provisions is

an estimated decrease in cost associated with changes to the HH QRP on average of \$12,016.33 per HHA annually, or \$145,986,343.50 for all HHAs annually.

Comment: A commenter stated that CMS had underestimated the cost of changes to the OASIS, adding that CMS had not considered training and opportunity costs related to data set changes.

Response: Our burden estimates reflect the burden on data submission. We intend to provide educational resources on the OASIS changes, including training and guidance, to providers at no cost.

D. Accounting Statements and Tables

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 30, 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 30 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 in CY 2018. Table 31 provides our best estimates of the changes associated with the HH QRP provisions.

TABLE 30—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2017 TO 2018

| Category | Transfers |
|---------------------------------|-----------------------------|
| Annualized Monetized Transfers. | -\$80 million. |
| From Whom to Whom? | Federal Government to HHAs. |

TABLE 31—ACCOUNTING STATEMENT: HH QRP CLASSIFICATION OF ESTIMATED COSTS, FROM CY 2018 TO 2019

| Category | Costs |
|--|-------------------|
| Annualized Monetized Net Burden for HHAs Submission of the OASIS | -\$146.0 million. |

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's PRA and economic analysis.

F. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this final rule is a decrease of 0.4 percent, or \$80 million, in Medicare

payments to HHAs for CY 2018. The -\$80 million impact reflects the effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision (\$100 million decrease), a 1 percent CY 2018 HH payment update percentage (\$190 million increase), and a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth (\$170 million decrease).

2. HHVBP Model

In conclusion, we estimate there will 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 2018. However, the overall economic impact of the HHVBP Model is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, for CY 2019 we estimate that there will be a total decrease in costs of \$145,986,343.50 associated with the changes to the HH QRP.

This analysis, together with the remainder of this preamble, provides a final Regulatory Flexibility Analysis.

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 substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 484

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 484 as set forth below:

PART 484—HOME HEALTH SERVICES

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

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

■ 2. Section 484.250 is amended by revising paragraph (a)(1) and adding paragraphs (d) through (f) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b) and (d) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

(d) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under section 1895(b)(3)(B)(v) of the Act for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date

that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

- (i) HHA CMS Certification Number (CCN).
- (ii) HHA Business Name.
- (iii) HHA Business Address.
- (iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (the address must be a physical address, not a post office box).

(v) HHA’s reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under section 1895(b)(3)(B)(v) of the Act and a justification for the proposed date.

(3) Except as provided in paragraph (d)(4) of this section, CMS will not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (d).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

- (i) An extraordinary circumstance affects an entire region or locale.
- (ii) A systemic problem with one of CMS’s data collection systems directly affected the ability of a HHA to submit data under section 1895(b)(3)(B)(v) of the Act.

(e) *Reconsideration.* (1) HHAs that do not meet the quality reporting requirements under section 1895(b)(3)(B)(v) of the Act for a program year will receive a letter of non-compliance via the United States Postal Service and notification in CASPER. An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov* containing all of the following information:

- (i) HHA CCN.
- (ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (the address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider an exception or extension request unless the HHA has complied fully with the requirements in paragraph (e)(2) of this section.

(4) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent via the United States Postal Service.

(f) *Appeals.* (1) A HHA that is dissatisfied with CMS’ decision on a request for reconsideration submitted under paragraph (e) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(2) [Reserved]

■ 3. Section 484.305 is amended by revising the definition of “Applicable measure” to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable measure means a measure for which a competing HHA has provided a minimum of—

(1) Twenty home health episodes of care per year for the OASIS-based measures;

(2) Twenty home health episodes of care per year for the claims-based measures; or

(3) Forty completed surveys for the HHCAPHS measures.

* * * * *

Dated: October 23, 2017.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: October 24, 2017.

Eric D. Hargan,
Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017-23935 Filed 11-1-17; 4:15 pm]

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