DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, 488, 498

[CMS–1611–F]

RIN 0938–AS14

Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies

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

ACTION: Final rule.

SUMMARY: This final rule updates Home Health Prospective Payment System (HH PPS) rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor under the Medicare prospective payment system for home health agencies (HHAs), effective for episodes ending on or after January 1, 2015. As required by the Affordable Care Act, this rule implements the second year of the four-year phase-in of the rebasing adjustments to the HH PPS payment rates. This rule provides information on our efforts to monitor the potential impacts of the rebasing adjustments and the Affordable Care Act mandated face-to-face encounter requirement. This rule also implements: Changes to simplify the face-to-face encounter regulatory requirements; changes to the HH PPS case-mix weights; changes to the home health quality reporting program requirements; changes to simplify the therapy reassessment timeframes; a revision to the Speech-Language Pathology (SLP) personnel qualifications; minor technical regulations text changes; and limitations on the reviewability of the civil monetary penalty provisions. Finally, this rule also discusses Medicare coverage of insulin injections under the HH PPS, the delay in the implementation of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM), and a HH value-based purchasing (HH VBP) model.

DATES: *Effective Date:* These regulations are effective on January 1, 2015.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Table of Contents

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
APU Annual Payment Update
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
CAD Coronary Artery Disease
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CASPER Certification and Survey Provider Enhanced Reports
CHF Congestive Heart Failure
CMI Case-Mix Index
CMN Certificate of Medical Necessity
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
COPD Chronic Obstructive Pulmonary Disease
CPI Center for Program Integrity
CVD Cardiovascular Disease
CY Calendar Year

DM Diabetes Mellitus
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DIF DME Information Form
DRA Deficit Reduction Act of 2005, Pub. L. 109–171, enacted February 8, 2006
FDL Fixed Dollar Loss
FI Fiscal Intermediaries
FR Federal Register
FY Fiscal Year
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCPCS Healthcare Common Procedure Coding System
HCIS Health Care Information System
HH Home Health
HHA Home Health Agency
HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHRG Home Health Resource Group
HIPPS Health Insurance Prospective Payment System
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
IRF Inpatient Rehabilitation Facility
IT Information Technology
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MEPS Medical Expenditures Panel Survey
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSS Medical Social Services
NQF National Quality Forum
NRS Non-Routine Supplies
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
OES Occupational Employment Statistics
OIG Office of Inspector General
OT Occupational Therapy
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health IT
MFP Multifactor productivity
PAMA Protecting Access to Medicare Act of 2014
PAC–PRD Post-Acute Care Payment Reform Demonstration
PEP Partial Episode Payment Adjustment
PT Physical Therapy
QAO Quality Assessments Only
QAP Quality Assurance Plan
PRRB Provider Reimbursement Review Board
RAP Request for Anticipated Payment
RF Renal Failure
RFA Regulatory Flexibility Act, Pub. L. 96—354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
SOC Start of Care
UMRA Unfunded Mandates Reform Act of 1995.

I. Executive Summary

A. Purpose

This rule updates the payment rates for HHAs for calendar year (CY) 2015, as required under section 1895(b) of the Social Security Act (the Act). This will reflect the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor finalized in the CY 2014 HH PPS final rule (78 FR 72256), required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the ''Affordable Care Act''). Updates to payment rates under the HH PPS will also include a change in the home health wage index to incorporate the new Office of Management and Budget (OMB) core-based statistical area (CBSA) definitions and updates to the payment rates by the home health payment update percentage reflective of the productivity adjustment mandated by 3401(e) of the Affordable Care Act.

This final rule also discusses: Our efforts to monitor the potential impacts of the Affordable Care Act mandated rebasing adjustments and the face-to-face encounter requirement (sections 3131(a) and 6407, respectively, of the Affordable Care Act); coverage of insulin injections under the HH PPS; and the delay in the implementation of the International Classification of Diseases, 10th Edition, Clinical Modification (ICD–10–CM) as a result of recent Congressional action (section 212 of the Protecting Access to Medicare Act, Public Law 113–93 (''PAMA'')). This final rule also: Simplifies the regulations at § 424.22(a)(1)(v) that govern the face-to-face encounter requirement mandated by section 6407 of the Affordable Care Act; recalibrates the HH PPS case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act; makes changes to the home health quality reporting program requirements under section 1895(b)(3)(B)(v)(II) of the Act; simplifies the therapy reassessment timeframes specified in regulation at § 409.44(c)(2)(C) and (D); revises the personnel qualifications for Speech-Language Pathology (SLP) at § 484.4; and makes minor technical changes to the regulations text at § 424.22(b)(1) and § 484.250(a)(1). This final rule will also place limitations on the reviewability of CMS's decision to impose a civil monetary penalty for noncompliance with Federal participation requirements. Finally, this rule discusses comments received on the HH Value-Based Purchasing (VBP) model.

B. Summary of the Major Provisions

As required by section 3131(a) of the Affordable Care Act and finalized in the CY 2014 HH final rule, ''Medicare and Medicaid Programs; Home Health Prospective Payment System Rate Update for CY 2014, Home Health Quality Reporting Requirements, and Cost Allocation of Home Health Survey Expenses'' (78 FR 77256, December 2, 2013), we are implementing the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor in section III.D.4. The rebasing adjustments for CY 2015 will reduce the national, standardized 60-day episode payment amount by $80.95, increase the national per-visit payment amounts by 3.5 percent of the national per-visit payment amounts in CY 2010 with the increases ranging from $1.79 for home health aide services to $6.34 for medical social services as described in section II.C, and reduce the NRS conversion factor by 2.82 percent.

This final rule also discusses our efforts to monitor the potential impacts of the rebasing adjustments and the Affordable Care Act mandated face-to-face encounter requirement in sections III.A. Section III B implements changes to the face-to-face encounter narrative requirement by eliminating the narrative as part of the certification of eligibility and by outlining procedures for obtaining documentation from the certifying physician and/or the acute/post-acute care facility that: (1) Establish that the patient was eligible for the home health benefit; and (2) demonstrate that the face-to-face encounter was related to the primary reason the patient requires home health services, occurred within the required timeframe, and was performed either by the certifying physician, an acute/post-acute care physician that cared for the patient in that setting, or allowed non-physician practitioner (NPP). In addition, associated physician claims for certification/re-certification of eligibility (patient not present) will not

be eligible to be paid when a patient does not meet home health eligibility criteria. We will also clarify that the face-to-face encounter requirement is applicable for all episodes initiated with the completion of a Start-of-Care OASIS assessment, which we consider certifications, not re-certifications. In section III.C of the 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. In section III.D.1 of this final rule, we are updating the payment rates under the HH PPS by the home health payment update percentage of 2.1 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.6 percent, minus 0.5 percentage point for productivity as required by section 1895(b)(3)(B)(vi)(I) of the Act. In section III.D.3 of this final rule, we are updating the home health wage index using a 50/50 blend of the existing core-based statistical area (CBSA) designations and the new CBSA designations set out in a February 28, 2013, Office of Management and Budget (OMB) bulletin.

This final rule also implements changes to the home health quality reporting program in section III.D.2, including the establishment of a minimum threshold for submission of OASIS assessments for purposes of quality reporting compliance, the establishment of a policy for the adoption of changes to measures that occur in-between rulemaking cycles as a result of the NQF process, and submission dates for the HHCAHPS Survey moving forward through CY 2017. In section III.E of this final rule, we discuss our rationale for maintaining the existing fixed-dollar loss (FDL) and loss-sharing ratios used in calculating high-cost outlier payments under the HH PPS. In section III.F, we discuss our recent analysis of home health claims identified with skilled nursing visits that appear to have been for the sole purpose of insulin injection assistance, without any secondary diagnoses indicating that the patient was physically or mentally unable to self-inject. We discuss, in section III.G of this final rule, the delay in the implementation of ICD–10–CM as a result of section 212 of PAMA. In section III.H of this final rule, we discuss our finalizing of a change in the therapy reassessment regulations by requiring that therapy reassessments are to occur at least every 30 calendar days. In section III.I of this final rule, we discuss a HH VBP model. In section III.J we discuss our revision to the personnel qualifications for SLP. In section III.K we discuss minor technical regulations text changes. In section III.L we discuss our revision to the civil monetary provisions, which place limitations on the reviewability of the civil monetary penalty imposed on a HHA for noncompliance with federal participation requirements.

C. Summary of Costs and Transfers

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision Description	Costs	Transfers
CY 2015 HH PPS Payment Rate Update.	A net reduction in burden of $21.55 million associated with certifying patient eligibility for home health services & certification form revisions.	The overall economic impact of this final rule is an estimated $60 million in decreased payments to HHAs.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Social Security Act (the Act), entitled ''Prospective Payment For Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels, respectively. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

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

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected for the year. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement

Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If a HHA does not submit quality data, the HH market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS; section 3131(c) of the Affordable Care Act amended 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. The amended section 421(a) of the MMA now requires, 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, that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section II.D.4.e). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode.

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

C. Updates to the HH PPS

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

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

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

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1—0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change will 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, CMS 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, CMS must phase in any adjustment over a four-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year as reflected in Table 2, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper.

TABLE 2—MAXIMUM ADJUSTMENTS TO THE NATIONAL PER-VISIT PAYMENT RATES (NOT TO EXCEED 3.5 PERCENT OF THE AMOUNT(S) IN CY 2010)

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

III. Provisions of the Proposed Rule and Responses to Comments

We received approximately 337 timely responses from the public, many of which contained multiple comments on the CY 2015 HH PPS proposed rule (79 FR 38366). Many of the comments were identical, but submitted by multiple commenters. We received comments from various trade associations, HHAs, individual registered nurses, physicians, clinicians, therapists, therapy assistants, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments received, and our responses.

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments and the Face-to-Face Encounter Requirement

1. Affordable Care Act Rebasing Adjustments

As we stated in the CY 2015 HH PPS proposed rule (79 FR 38370), we do not have a sufficient amount of CY 2014 home health claims data to analyze as part of our effort in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293). However, we analyzed 2012 home health agency cost report data to determine whether the average cost per episode was higher using 2012 cost report data compared to the 2011 cost report data used in calculating the rebasing adjustments. Specifically, we re-estimated the cost of a 60-day episode using 2012 cost report and 2012 claims data, rather than using 2011 cost report and 2012 claims data. To determine the 2012 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 2012 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative. The 2012 average number of visits was taken from 2012 claims data. We estimate the cost of a 60-day episode to be $2,413.82 using 2012 cost report data (Table 3).

TABLE 3—AVERAGE COSTS PER VISIT AND AVERAGE NUMBER OF VISITS FOR A 60-DAY EPISODE

Discipline	2012 Average costs per visit	2012 Average number of visits	2012 60-day episode costs
Skilled Nursing	$130.49	9.55	$ 1,246.18
Home Health Aide	61.62	2.60	160.21
Physical Therapy	160.03	4.80	768.14
Occupational Therapy	157.78	1.09	171.98
Speech-Language Pathology	172.08	0.22	37.86
Medical Social Services	210.36	0.14	29.45
Total			2,413.82

Source: FY 2012 Medicare cost report data and 2012 Medicare claims data from the standard analytic file (as of June 2013) for episodes ending on or before December 31, 2012 for which we could link an OASIS assessment.

Using the current claims data for CY 2013 (as of June 30, 2014), we re-examined the 2012 visit distribution and re-calculated the 2013 estimated cost per episode using the updated 2013 visit profile. We estimate the 2013 60-day episode cost to be $2,485.24 (Table 4).

TABLE 4—2013 ESTIMATED COST PER EPISODE

Discipline	2012 Average costs per visit	2013 Average number of visits	2013 HH Market basket	2013 Estimated cost per episode
Skilled Nursing	$130.49	9.28	1.023	$1,238.80
Home Health Aide	61.62	2.41	1.023	151.92
Physical Therapy	160.03	5.03	1.023	823.46
Occupational Therapy	157.78	1.22	1.023	196.92
Speech-Language Pathology	172.08	0.25	1.023	44.01
Medical Social Services	210.36	0.14	1.023	30.13
Total				2,485.24

Source: FY 2012 Medicare cost report data and 2013 Medicare claims data from the standard analytic file (as of June 30, 2014) for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes) ending on or before December 31, 2013 for which we could link an OASIS assessment.

In the CY 2014 HH PPS final rule (78 FR 72277), using 2011 cost report data, we estimated the 2012 60-day episode cost to be about $2,507.83 ($2,453.71 * 0.9981 * 1.024) and the 2013 60-day episode cost to be $2,565.51 ($2,453.71 * 0.9981 * 1.024 * 1.023). Using 2012 cost report data, the 2012 and 2013 estimated cost per episode ($2,413.82 and $2,485.24, respectively) are lower than the episode costs we estimated using 2011 cost report data for the CY 2014 HH PPS final rule.[1]

In the CY 2014 HH PPS final rule, we stated that our analysis of 2011 cost report data and 2012 claims data indicated a need for a −3.45 percent rebasing adjustment to the national, standardized 60-day episode payment rate each year for four years. However, as specified by statute, the rebasing adjustment is limited to 3.5 percent of the CY 2010 national, standardized 60-day episode payment rate of $2,312.94 (74 FR 58106), or $80.95. We stated that given that a −3.45 percent adjustment for CY 2014 through CY 2017 will result in larger dollar amount reductions than the maximum dollar amount allowed under section 3131(a) of the Affordable Care Act of $80.95, we are limited to implementing a reduction of $80.95 (approximately 2.8 percent for CY 2014) to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017. Our latest analysis of 2012 cost report and 2013 claims data suggests that an even larger reduction (−4.21 percent) than the reduction described in the CY 2014 final rule (−3.45 percent) will be needed in order to align payments to costs. We stated in the CY 2015 HH PPS proposed rule that we would continue to monitor potential impacts of rebasing as more data become available (79 FR 38371).

Although we finalized the rebasing adjustments in the CY 2014 HH PPS final rule and did not propose any changes to those adjustments, we received a number of comments on the rebasing and on our analysis of 2012 cost report data in the CY 2015 HH PPS proposed rule. Those comments and our responses are summarized below.

Comment: Commenters urged CMS to postpone or stop the implementation of the rebasing reductions. Commenters expressed concerns with the rebasing methodology, impact analysis, and process outlined in the CY 2014 HH PPS proposed and final rules and stated that a more comprehensive study is needed to evaluate the rebasing reductions. Some commenters also stated that the findings on the study on access to care mandated by section 3131(d) of the Affordable Care Act were not fully considered prior to the implementation or rebasing and urged CMS to take into account these findings and reconsider the rebasing adjustments.

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

Comment: Several commenters were concerned with the impact of the rebasing adjustments and urged CMS to monitor the impact of the reductions and provided suggestions for the impact and monitoring analyses.

Response: As we noted in the CY 2015 HH PPS proposed rule, sufficient claims data for CY 2014 is not available for analysis. We plan to provide an update on our monitoring efforts once sufficient CY 2014 claims data become available. In their public comments on the CY 2015 HH PPS proposed rule, MedPAC stated that given the 12 percent or higher margins for for-profit and non-profit agencies in 2012, they do not expect the reductions to materially affect the operations of most agencies and recommended to Congress that rebasing be implemented in a shorter period, that the annual payment update be eliminated, and that such changes to statute would help bring payments closer to costs than the current approach to rebasing. MedPAC is required to conduct a study and submit a report on the impact of the rebasing adjustments on access to care, quality outcomes, the number of home health agencies, and rural agencies, urban agencies, for-profit agencies and non-profit agencies to be submitted no later than January 1, 2015.

Comment: A commenter stated that CMS did not indicate in the CY 2015 HH PPS proposed rule how many 2012 cost reports were audited and how many were trimmed out (excluded) from the analysis. The commenter requested that CMS include this information in the final rule for the sake of transparency.

Response: None of the 2012 cost reports were audited. Of the 10,485 cost reports in the sample, which contained 10,310 unique provider numbers, 6,135 cost reports were used in the results presented in the CY 2015 HH PPS proposed rule (79 FR 38370–38371). We used same trimming and weighting methodology described in the CY 2014 HH PPS proposed rule (78 FR 40284–40286).

Comment: Commenters expressed concern with the reduction to the NRS conversion factor. The commenter was concerned that reductions to payments for NRS may impact patients with wounds and requested that CMS re-

[1] The 2012 estimated cost per episode cited is based on FY 2012 cost report data and CY 2012 claims data (as of June 30, 2013) and the 2013 estimated cost per episode is based on FY 2012 cost report data and CY 2013 claims data (as of June 30, 2014).

evaluate the utilization of and charges associated with surgical dressings compared to other supplies in the NRS group and suggested CMS consider a separate conversion factor for surgical dressings. Another commenter stated that it is difficult to determine whether actual hospital-based HHA NRS costs had been included into the total cost of services measured. The commenter stated that there is a flaw in the hospital-based cost report where the NRS cost data does not flow to the total cost. The commenter recommended that CMS review the hospital based cost reports for this problem and fix the NRS adjustment equitably if that flaw exists.

Response: We researched whether hospital-based HHA costs for NRS were included in our rebasing calculations in the CY 2014 HH PPS proposed and final rules. We noted in the CY 2014 HH PPS final rule that NRS costs for hospital-based HHAs are to be reported on CMS form 2552–10, worksheet H, line 12 (78 FR 72291). This data flows to worksheet H3, part 1, line 15. However, line 15, columns 6 through 11 are shaded out and not currently populated. We are in the process of ''un-shading'' those columns for future data collection. Of the over 11,000 HHAs included in the Regulatory Impact Analysis in section V., less than 10 percent are facility-based HHAs. We believe that using NRS cost data solely from freestanding HHAs, given the unavailability of the hospital-based HHA NRS cost data for FY 2011, is appropriate. We examined cost report data for both freestanding and hospital-based HHAs (using instances where the hospital-based HHA submitted cost report data using the older version of the Medicare hospital cost report (CMS form 2552–96) that allows columns 6 through 11 on line 15 on worksheet H6 part 1to be populated). We found that the average NRS cost per visit varies substantially from year-to-year, with the five-year average NRS cost per visit at $2.27.

Once the hospital-based cost report data becomes available, we will analyze those costs and take them into consideration as we work to address any findings from the home health study required by section 3131(d) of the Affordable Care Act, monitor the potential impact of the rebasing adjustments and other recent payment changes, and develop payment options to ensure ongoing access to care for vulnerable populations. The work may include potential revisions to the NRS and case-mix weights methodology to better reflect costs of treating Medicare beneficiaries.

Comment: Commenters urged CMS to use the authority granted under section 1871 of the Social Security Act to modify the rebasing adjustments finalized in the CY 2014 HH PPS final rule. The commenter stated that CMS has authority to modify final regulations if CMS finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. Commenters urged CMS to modify payment rates in order to secure seniors' access to home health care, ensure high quality of care, and preserve jobs. Another commenter stated that section 1895 of the Social Security Act allows CMS to implement a less aggressive approach to rebasing.

Response: Section 1871(b)(2)(C) of the Act cross-references section 553(b)(3)(B) of the Administrative Procedure Act. Both the Social Security Act and the Administrative Procedure Act permit us to waive the requirements of notice and a period for comment if, among other things, the Secretary determines that notice and comment are impracticable, unnecessary, or contrary to the public interest. Normally, we only waive notice and comment when we believe there are unusual circumstances that would warrant expedited implementation of a rule, or when the rule changes are technical and/or involve no exercise of discretion on the part of the Secretary. In the context of this notice-and-comment rulemaking, it appears that the commenter is requesting that we adjust our rebasing rates without having previously announced our intention to do so. We do not believe that circumstances have changed in a way that would require an immediate change to our rebasing rate; and even if circumstances changed, we do not believe that changing the rate without a period for notice and comment would be in the public interest. We also note that calculation of the rates pursuant to the rebasing provision at section 1895(b)(3)(A)(iii) of the Act took place after a period of notice and comment in the CY 2014 HH PPS rule (see 78 FR 72278 through 72281). Section 1895 of the Act states that we must phase in any adjustment over a four-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. We do not have the authority to implement rebasing in another manner. Therefore, we will move forward with the rebasing reductions finalized in the CY 2014 HH PPS final rule.

2. Affordable Care Act Face-to-Face Encounter Requirement

Effective January 1, 2011, section 6407 the Affordable Care Act requires that, as a condition for payment, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself, or an allowed non-physician practitioner (NPP), as described below, had a face-to-face encounter with the patient. The regulations at § 424.22(a)(1)(v) currently require that that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care. In addition, as part of the certification of eligibility, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in subsections 1814(a) and 1835(a) of the Act, and in need of either intermittent skilled nursing services or therapy services, as defined in § 409.42(c). The face-to-face encounter requirement was enacted, in part, to discourage physicians certifying patient eligibility for the Medicare home health benefit from relying solely on information provided by the HHAs when making eligibility determinations and other decisions about patient care.

In the CY 2011 HH PPS final rule, in which we implemented the face-to-face encounter provision of the Affordable Care Act, some commenters expressed concern that this requirement would diminish access to home health services (75 FR 70427). We examined home health claims data from before implementation of the face-to-face encounter requirement (CY 2010), the year of implementation (CY 2011), and the years following implementation (CY 2012 and CY 2013), to determine whether there were indications of access issues as a result of this requirement. Nationally, utilization (as measured by the number of episodes) held relatively constant over the first year of implementation (comparing CY 2010 and CY 2011) (see Table 5 below). Between CY 2010 and CY 2013, there was a 1.8 percent decrease in number of episodes, however, there was a 1.5 percent increase in the number of home health users (beneficiaries with at least one home health episode). Also, the number of HHAs providing at least one home health episode increased steadily from CY 2010 through CY 2013 with an

aggregate increase of 8.9 percent (see Table 5 below).

Home health users as a percentage of Part A and/or Part B fee-for-service (FFS) beneficiaries decreased slightly from 9.3 percent in CY 2010 to 9.0 percent in CY 2013. The number of episodes per Part A and/or Part B FFS beneficiaries decreased slightly between CY 2010 and CY 2013, with 0.19 (or 19 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) in CY 2010 and 0.17 (or 17 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) in CY 2013. We note these observed decreases between CY 2010 to CY 2013, for the most part, are likely the result of an increase in FFS enrollment between CY 2010 and CY 2013 of 4.6 percent. Newly eligible Medicare beneficiaries are typically not of the age where home health services are needed and therefore, without any changes in utilization, we will expect home health users and the number of episodes per Part A and/or B FFS beneficiaries to decrease with an increase in the number of newly enrolled FFS beneficiaries.

TABLE 5—HOME HEALTH STATISTICS, CY 2010 THROUGH CY 2013

	2010	2011	2012	2013
Number of episodes	6,833,669	6,821,459	6,727,875	6,708,923
Beneficiaries receiving at least 1 episode (Home Health Users)	3,431,696	3,449,231	3,446,122	3,484,579
Part A and/or B FFS beneficiaries	36,818,078	37,686,526	38,224,640	38,505,609
Episodes per Part A and/or B FFS beneficiaries	0.19	0.18	0.18	0.17
Home health users as a percentage of Part A and/or B FFS beneficiaries	9.3%	9.2%	9.0%	9.0%
HHAs providing at least 1 episode	10,916	11,446	11,746	11,889

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

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

Although home health utilization at the national level decreased slightly from CY 2010 and CY 2013, the decrease in utilization did not occur in all states. For example, California, New Jersey and Virginia experienced an increase in the number of episodes from CY 2010 to CY 2013. Also, the number of episodes per Part A and/or Part B FFS beneficiaries for these states increased or remained roughly the same between CY 2010 through CY 2013 (see Table 6).

TABLE 6—HOME HEALTH STATISTICS FOR SELECT STATES WITH INCREASING NUMBERS OF HOME HEALTH EPISODES BETWEEN CY 2010 AND CY 2011

	Year	AL	CA	MA	NJ	VA
Number of Episodes	2010	149,242	428,491	183,271	142,328	142,660
	2011	151,131	451,749	186,849	143,127	149,154
	2012	151,812	477,732	183,625	142,129	154,677
	2013	148,972	508,838	186,871	143,674	160,105
Beneficiaries Receiving at Least 1 Episode (Home Health Users)	2010	68,949	259,013	103,954	95,804	83,933
	2011	70,539	270,259	107,520	97,190	86,796
	2012	71,186	281,023	106,910	96,534	89,879
	2013	71,703	294,150	110,573	97,385	94,393
Part A and/or Part B FFS Beneficiaries	2010	689,302	3,199,845	890,472	1,205,049	1,014,248
	2011	717,413	3,294,574	934,312	1,228,239	1,055,516
	2012	732,952	3,397,936	959,015	1,232,950	1,086,474
	2013	739,868	3,444,078	976,814	1,245,275	1,119,886
Episodes per Part A and/or Part B FFS beneficiaries	2010	0.22	0.13	0.21	0.12	0.14
	2011	0.21	0.14	0.20	0.12	0.14
	2012	0.21	0.14	0.19	0.12	0.14
	2013	0.20	0.15	0.19	0.12	0.14
Home Health Users as a Percentage of Part A and/or B FFS beneficiaries	2010	10.00%	8.09%	11.67%	7.95%	8.28%
	2011	9.83%	8.20%	11.51%	7.91%	8.22%
	2012	9.71%	8.27%	11.15%	7.83%	8.27%
	2013	9.69%	8.54%	11.32%	7.82%	8.43%
Providers Providing at Least 1 Episode	2010	148	925	138	49	196
	2011	150	1,013	150	48	209
	2012	148	1,073	160	47	219
	2013	150	1,157	165	46	224

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

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

The states with the highest utilization of Medicare home health (as measured by the number of episodes per Part A and/or Part B FFS beneficiaries) are Texas, Florida, Oklahoma, Mississippi, and Louisiana (Table 7 and Figure 1 below). In aggregate, for CY 2010 through CY 2013 the number of episodes for these states decreased by 8.0 percent; however, even with this decrease from CY 2010 through CY 2013, the five states listed in Table 7 continue to be among the states with the highest utilization of Medicare home health nationally (see Figure 1). If we were to exclude the five states listed in Table 7 from the national figures in Table 5, home health users (beneficiaries with at least one home health episode) as a percentage of Part A and/or Part B fee-for-service (FFS) beneficiaries would decrease from to 9.0 percent to 8.1 percent for CY 2013 and the number of episodes per Part A and/or Part B FFS beneficiaries would decrease from 0.17 (or 17 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) to 0.14 (or 14 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) for CY 2013.

Texas, accounting for roughly 17 percent of HHA episodes in 2010, experienced a 12 percent decrease in the number of episodes and a 9 percent decrease in the number of home health users between CY 2010 and CY 2013 (see Table 7 below). We also note that Texas is one of the states that has areas with suspect billing practices. A temporary moratoria on enrollment of new HHAs, effective July 30, 2013, were put in place for Miami, FL and Chicago, IL. In January of 2014, CMS announced new temporary moratoria on enrollment of new HHAs in four additional areas —Fort Lauderdale, FL; Detroit, MI; Dallas, TX; and Houston, TX. If we were to exclude Texas from the national average (see Table 5 above), there would be a 0.13 percent increase in number of episodes between CY 2010 and CY 2013 rather than a 1.8 percent decrease as observed at the national level. The number of home health users would increase 2.8 percent compared to the national average with an increase of 1.5 percent.

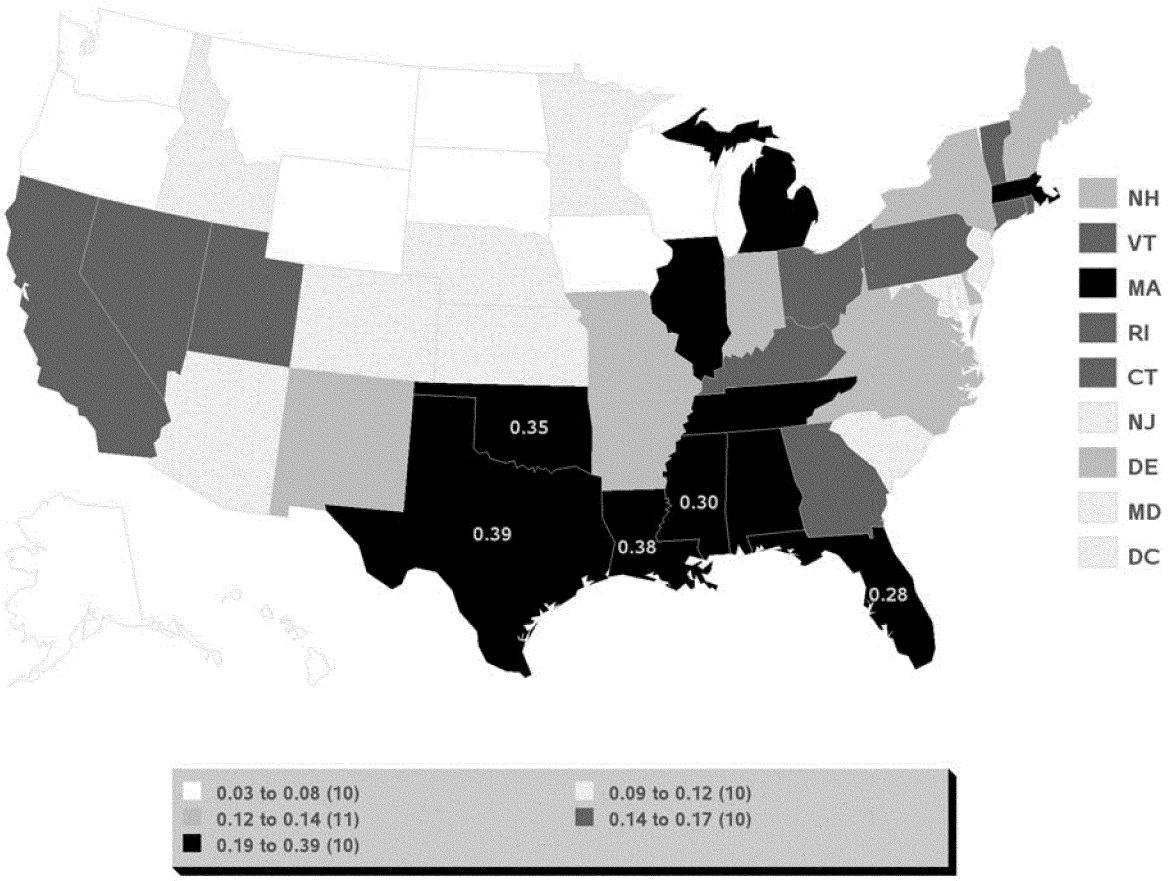
TABLE 7—HOME HEALTH STATISTICS FOR THE STATES WITH THE HIGHEST NUMBER OF HOME HEALTH EPISODES PER PART A AND/OR PART B FFS BENEFICIARIES, CY 2010 THROUGH CY 2013

	Year	TX	FL	OK	MS	LA
Number of Episodes	2010	1,127,852	689,183	208,555	153,169	256,014
	2011	1,107,605	701,426	203,112	153,983	249,479
	2012	1,054,244	691,255	196,887	148,516	230,115
	2013	995,555	689,269	196,713	143,428	215,590
Beneficiaries Receiving at Least 1 Episode (Home Health Users)	2010	366,844	355,181	68,440	55,132	77,976
	2011	363,474	355,900	67,218	55,818	77,677
	2012	350,803	354,838	65,948	55,438	74,755
	2013	333,396	357,099	66,502	55,453	73,888
Part A and/or Part B FFS Beneficiaries	2010	2,500,237	2,422,141	533,792	465,129	544,555
	2011	2,597,406	2,454,124	549,687	476,497	561,531
	2012	2,604,458	2,451,790	558,500	480,218	568,483
	2013	2,535,611	2,454,216	568,815	483,439	574,654
Episodes per Part A and/or Part B FFS beneficiaries	2010	0.45	0.28	0.39	0.33	0.47
	2011	0.43	0.29	0.37	0.32	0.44
	2012	0.40	0.28	0.35	0.31	0.40
	2013	0.39	0.28	0.35	0.30	0.38
Home Health Users as a Percentage of Part A and/or Part B FFS Beneficiaries	2010	14.67%	14.66%	12.82%	11.85%	14.32%
	2011	13.99%	14.50%	12.23%	11.71%	13.83%
	2012	13.47%	14.47%	11.81%	11.54%	13.15%
	2013	13.15%	14.55%	11.69%	11.47%	12.86%
Providers Providing at Least 1 Episode	2010	2,352	1,348	240	53	213
	2011	2,472	1,426	252	51	216
	2012	2,549	1,430	254	48	213
	2013	2,600	1,357	262	48	210

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

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

Figure 1: Home Health Episodes per Part A and/or Part B FFS Beneficiaries - CY 2013



For CY 2011, in addition to the implementation of the Affordable Care Act face-to-face encounter requirement, HHAs were also subject to new therapy reassessment requirements, payments were reduced to account for increases in nominal case-mix, and the Affordable Care Act mandated that the HH PPS payment rates be reduced by 5 percent to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments. The estimated net impact to HHAs for CY 2011 was a decrease in total HH PPS payments of 4.78 percent. Therefore, any changes in utilization between CY 2010 and CY 2011 cannot be solely attributable to the implementation of the face-to-face encounter requirement. For CY 2012 we recalibrated the case-mix weights, including the removal of two hypertension codes from scoring points in the HH PPS Grouper and lowering the case-mix weights for high therapy cases estimated net impact to HHAs, and reduced HH PPS rates in CY 2012 by 3.79 percent to account for additional growth in aggregate case-mix that was unrelated to changes in patients' health status. The estimated net impact to HHAs for CY 2012 was a decrease in total HH PPS payments of 2.31 percent. Again, any changes in utilization between CY 2011 and CY 2012 cannot be solely attributable to the implementation of the face-to-face encounter requirement. Given that a decrease in the number of episodes from CY 2010 to CY 2013 occurred in states that have the highest home health utilization (number of episodes per Part A and/or Part B FFS beneficiaries) and not all states experienced declines in episode volume during that time period, we believe that the implementation of the face-to-face encounter requirement could be considered a contributing factor. We will continue to monitor for potential impacts due to the implementation of the face-to-face encounter requirements and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Changes to the Face-to-Face Encounter Requirements

1. Background on Statutory and Regulatory Requirements

As a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself or an allowed non-physician practitioner (NPP) had a face-to-face encounter with the patient. Specifically, sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as amended by the Affordable Care Act, state that, in addition to the certifying physician, a nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by state law, or a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the

physician may perform the face-to-face encounter.

The goal of the Affordable Care Act provision is to achieve greater physician accountability in certifying a patient's eligibility and in establishing a patient's plan of care. We believe this goal is better achieved if the face-to-face encounter occurs close to the start of home health care, increasing the likelihood that the clinical conditions exhibited by the patient during the encounter are related to the primary reason the patient needs home health care. The certifying physician is responsible for determining whether the patient meets the eligibility criteria (that is, homebound status and need for skilled services) and for understanding the current clinical needs of the patient such that the physician can establish an effective plan of care. As such, CMS regulations at § 424.22(a)(1)(v) require that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care. In addition, current regulations require that, as part of the certification of eligibility, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in sections 1835(a) and 1814(a) of the Act, and in need of either intermittent skilled nursing services, physical therapy, or speech-language pathology services, as defined in § 409.42(c).

The ''Requirements for Home Health Services'' describes certifying a patient's eligibility for the Medicare home health benefit, and as stated in the ''Content of the Certification'' under § 424.22 (a)(1), a physician must certify that:

- The individual needs or needed intermittent skilled nursing care, physical therapy, and/or speech-language pathology services as defined in § 409.42(c).
- Home health services are or were required because the individual was confined to the home (as defined in sections 1835(a) and 1814(a) of the Act), except when receiving outpatient services.
- A plan for furnishing the services has been established and is or will be periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine (a doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law).[2]
- Home health services will be or were furnished while the individual is or was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.
- A face-to-face patient encounter occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was related to the primary reason the patient requires home health services. This also includes documenting the date of the encounter and including an explanation of why the clinical findings of such encounter support that the patient is homebound (as defined in sections 1835(a) and 1814(a) of the Act) and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(c). The documentation must be clearly titled and dated and the documentation must be signed by the certifying physician.

CMS regulations at § 424.22(a)(1)(i) also require that, for instances where the physician orders skilled nursing visits for management and evaluation of the patient's care plan,[3] the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately after the narrative in the addendum.

When there is a continuous need for home health care after an initial 60-day episode of care, a physician is also required to recertify the patient's eligibility for the home health benefit. In accordance with § 424.22(b), a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. In recertifying the patient's eligibility for the home health benefit, the recertification must indicate the continuing need for skilled services and estimate how much longer the skilled services will be required. The need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care, physical therapy, or speech–language pathology services. Again, for instances where the physician ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately after the narrative in the addendum.

In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs (as defined by the Act and discussed above), the physician who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health care, and who had privileges in such facility, could also perform the face-to-face encounter. In the CY 2013 HH PPS final rule (77 FR 67068) we revised our regulations so that an allowed NPP, collaborating with or under the supervision of the physician who cared for the patient in the acute/post-acute care facility, could communicate the clinical findings that supported the patient's needs for skilled care and homebound status to the acute/post-acute care physician. In turn, the acute/post-acute care physician would communicate the clinical findings that supported the patient's needs for skilled care and homebound status from the encounter performed by the NPP to the certifying physician to document. Policy always permitted such NPPs in the acute/post-acute care setting from which the patient is directly admitted to home health care to perform the face-to-face encounter and communicate directly with the certifying physician the clinical findings from the encounter and how such findings support that the patient was homebound and needed skilled services (77 FR 67106).

[2] The physician cannot have a financial relationship as defined in § 411.354 of the chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

[3] Skilled nursing visits for management and evaluation of the patient's care plan are reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential *unskilled* care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition (reference § 409.33 and section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual (Pub. 100–02)).

2. Changes to the Face-to-Face Encounter Narrative Requirement and Non-Coverage of Associated Physician Certification/Re-Certification Claims

Each year, the CMS' Office of Financial Management (OFM), under the Comprehensive Error Rate Testing (CERT) program, calculates the Medicare Fee-for-Service (FFS) improper payment rate. For the FY 2013 report period (reflecting claims processed between July 2011 and June 2012), the national Medicare FFS improper payment rate was calculated to be 10.1 percent.[4] For that same report period, the improper payment rate for home health services was 17.3 percent, representing a projected improper payment amount of approximately $3 billion.[5] The improper payments identified by the CERT program represent instances in which a health care provider fails to comply with the Medicare coverage and billing requirements and are not necessarily a result of fraudulent activity.[6]

The majority of home health improper payments were due to ''insufficient documentation'' errors. ''Insufficient documentation'' errors occur when the medical documentation submitted is inadequate to support payment for the services billed or when a specific documentation element that is required (as described above) is missing. Most ''insufficient documentation'' errors for home health occurred when the narrative portion of the face-to-face encounter documentation did not sufficiently describe how the clinical findings from the encounter supported the beneficiary's homebound status and need for skilled services, as required by § 424.22(a)(1)(v).

The home health industry continues to voice concerns regarding the implementation of the Affordable Care Act face-to-face encounter documentation requirement. The home health industry cites challenges that HHAs face in meeting the face-to-face encounter documentation requirements regarding the required narrative, including a perceived lack of established standards for compliance that can be adequately understood and applied by the physicians and HHAs. In addition, the home health industry conveys frustration with having to rely on the physician to satisfy the face-to-face encounter documentation requirements without incentives to encourage physician compliance. Correspondence received to date has expressed concern over the ''extensive and redundant'' narrative required by regulation for face-to-face encounter documentation purposes when detailed evidence to support the physician certification of homebound status and medical necessity is available in clinical records. In addition, correspondence stated that the narrative requirement was not explicit in the Affordable Care Act provision requiring a face-to-face encounter as part of the certification of eligibility and that a narrative requirement goes beyond Congressional intent.

While we do not agree that the narrative requirement goes beyond Congressional intent, we agree that there should be sufficient evidence in the patient's medical record to demonstrate that the patient meets the Medicare home health eligibility criteria. Therefore, in an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, we proposed that:

(1) The narrative requirement in regulation at § 424.22(a)(1)(v) would be eliminated. The certifying physician would still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility.

For instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician would still be required to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2). This requirement was implemented in the CY 2010 HH PPS final rule (74 FR 58111) and is not changing. We note that this requirement predates the Affordable Care Act, and is a long-established policy of CMS.

(2) In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, we proposed to review only the medical record for the patient from the certifying physician or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health) used to support the physician's certification of patient eligibility, as described in paragraphs (a)(1) and (b) of the section. If the patient's medical record, used by the physician in certifying eligibility, was not sufficient to demonstrate that the patient was eligible to receive services under the Medicare home health benefit, payment would not be rendered for home health services provided.

(3) Physician claims for certification/recertification of eligibility for home health services (G0180 and G0179, respectively) would not be covered if the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. However, rather than specify this in our regulations, this proposal would be implemented through future sub-regulatory guidance. We believed that these proposals were responsive to home health industry concerns regarding the face-to-face encounter requirements articulated above. We invited comment on these proposals and the associated change in the regulations text at § 424.22 the CY 2015 HH PPS proposed rule (79 FR 38376).

The following is a summary of the comments we received regarding (1) the proposed elimination of the face-to-face encounter narrative requirement as part of the certification of eligibility; and (2) the proposal to review only the medical record for the patient from the certifying physician or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health), used to support the physician's certification of patient eligibility, in determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care.

Comment: A few commenters urged CMS to remove the face-to-face requirement entirely. Commenters went on to note that since the intent of the face-to-face encounter is to combat fraud, CMS should be able to determine which HHAs are providing care by fraudulent means and should investigate those HHAs.

[4] U.S. Department of Health and Human Services, ''*FY 2013 Agency Financial Report''*, accessed on April, 23, 2014 at: *http://www.hhs.gov/afr/2013-hhs-agency-financial-report.pdf*.

[5] U.S. Department of Health and Human Services, ''*The Supplementary Appendices for the Medicare Fee-for-Service 2013 Improper Payment Rate Report''*, accessed on April, 23, 2014 at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/November2013ReportPeriodAppendixFinal12-13-2013_508Compliance_Approved12-27-13.pdf*.

[6] The CERT improper payment rate is not a ''fraud rate,'' but is a measurement of payments made that did not meet Medicare requirements. The CERT program cannot label a claim fraudulent.

Response: As we note above, as a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself or an allowed NPP had a face-to-face encounter with the patient. As such, we do not have the legal authority to eliminate the face-to-face encounter requirement. We also note above that the goal of this provision was to achieve greater physician accountability in certifying a patient's eligibility, increasing communication between the physician and home health agency to improve patient care, and in establishing a patient's plan of care. CMS's Center for Program Integrity (CPI) is currently engaged in a variety of activities aimed at reducing fraud and abuse. Such activities include provider/contractor audits, policy reviews, and the identification and monitoring of program vulnerabilities. CPI is actively collaborating with the U.S. Department of Justice, the Department of Health & Human Services' Office of Inspector General, state law enforcement agencies, other federal entities, and other CMS component(s) for the purposes of detecting, deterring, monitoring and combating fraud and abuse, as well as taking action against those that commit or participate in fraudulent or other unlawful activities.

Comment: Several commenters stated that CMS overstepped its statutory authority by requiring the face-to-face encounter narrative as part of the certification of patient eligibility for the home health benefit.

Response: We disagree with the commenters. We believe that our policy is consistent with the text, structure, and purpose of the statute. As a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must ''document'' that the physician himself or herself or an allowed NPP had a face-to-face encounter with the patient. The statutory text does not specify what the statutory term ''document'' means and we believe it is reasonable to interpret the requirement to ''document'' the face-to-face encounter as requiring the certifying physician to explain why the Medicare beneficiary is homebound and in need of skilled home health services. This interpretation is supported by the structure and purpose of the statute. Medicare payment for home health services is intended for individuals who are confined to the home and need skilled home health services. The face-to-face requirement and the documentation requirement help ensure that individuals do not receive home health services unnecessarily and that Medicare makes payment appropriately (that is, when the patient is homebound and needs skilled home health services). Nothing in the text of the statute indicates that the current required explanation is outside the scope of the Secretary's legal authority. In addition, this is similar to the long-standing Medicare policy for skilled nursing visits for management and evaluation of the patient's care plan (where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose), which was previously accepted by the home health community.

Comment: Nearly all commenters were supportive of the proposal to eliminate the face-to-face encounter narrative as part of the certification of eligibility and urged CMS to finalize the proposal. Commenters cited challenges in getting certifying physicians, whom the HHA has no control over, to document the narrative sufficiently. Other commenters noted that policies surrounding the narrative requirement contained confusing nuances and reviews of narrative sufficiency were too subjective. Some commenters noted instances where medical necessity and patient eligibility for the Medicare home health benefit were clearly demonstrated in the medical record; however, the entire claim was denied because the certifying physician's narrative was deemed insufficient.

In contrast, in its comments, MedPAC stated that the narrative should continue to be a requirement as part of the certification of eligibility for Medicare home health services. MedPAC stated that eliminating the narrative increases the risk of unnecessary or unauthorized home health care services. MedPAC suggested that CMS keep the current narrative requirement in effect for at least another year while it considers other potential improvements. Another commenter also disagreed with the proposed elimination of the face-to-face encounter narrative as part of the certification of eligibility stating that the elimination of the narrative may increase confusion about the Medicare home health eligibility requirements.

Response: We thank the vast majority of the commenters for their support of this proposal. As explained in the proposed rule, we proposed to eliminate the narrative requirement in an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements. We believe that the current narrative requirement can be useful for HHAs and medical review auditors, and is a permissible interpretation of section 6407 of the Affordable Care Act. However, as the proposed rule reflects, we acknowledge the concerns expressed by stakeholders regarding application of the narrative requirement. Balancing the considerations raised by stakeholders and commenters in light of our experience, we are finalizing our proposal to eliminate the narrative requirement. We will continue to evaluate whether further policy changes are warranted in the future.

Comment: A few commenters asked that CMS affirm that a narrative for instances where the physician is ordering skilled nursing for management and evaluation of the patient's care plan (that is, instances where the patient's underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose) should be a rare occurrence and asked how physicians and HHAs should identify cases that would require a narrative. Some commenters requested that CMS affirm in the final rule that while CMS proposed to eliminate the face-to-face encounter narrative, a narrative will still be required for instances where the physician is ordering skilled nursing visits for the management and evaluation of the patient's care plan. Several commenters recommended that CMS eliminate all narrative requirements for home health for consistency and to promote a better understanding of the certification/re-certification requirements by physicians.

Response: Instances where a physician is ordering skilled nursing for the management and evaluation of the patient's care plan (when the patient's underlying conditions and/or complications require a registered nurse to ensure that non-skilled care is achieving its purpose), should be rare and therefore a narrative that explains the need for such services as part of the certification/re-certification of patient eligibility for the Medicare home health benefit should also be rare. Analysis of CY 2012 home health claims data showed that only 1.5 percent of all home health visits were for management & evaluation of the patient's care plan (see Table 8 below).

TABLE 8—PERCENTAGE OF HOME HEALTH VISITS BY HCPCS CODE, CY 2012

Type of visit	Percent of total
G0154—Direct skilled services provided by a RN/LPN	67.6
G0162—Skilled services by a RN for management and evaluation of the plan of care (the patient's underlying conditions or complications requires an RN to ensure that essential non-skilled care achieves its purpose)	1.5
G0163—Skilled services of a RN/LPN for the observation and assessment of the patient's condition (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment)	10.5
G0164—Skilled services of a RN/LPN, in the training and/or education of a patient or family member	20.4

Source: CY 2012 Medicare claims data for episodes ending on or before December 31, 2012 (as of June 30, 2013) for which we had a linked OASIS assessment.

Note(s): RN = Registered Nurse, LPN = Licensed Practical Nurse.

We note that section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual provides information on how to identify whether the patient is receiving skilled nursing services for management and evaluation of the patient's care plan. Skilled nursing services in such instances can be ''reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition.'' [7] Section 40.1.2.2 also provides several examples in which skilled nursing services for management and evaluation of the patient's care plan could be considered reasonable and necessary.

As indicated above in Table 8, instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan should be infrequent. Because the purpose of these visits require a skilled nurse to ensure that unskilled care is achieving its purpose, we believe that it is still appropriate for the physician to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2).

Comment: Several commenters stated that CMS should halt current medical review activities with regard to the face-to-face encounter narrative and reopen any past denials that were made based on an insufficient face-to-face encounter narrative by making the implementation of the elimination of the face-to-face encounter narrative retroactive.

Response: The changes finalized in CY 2015 HH PPS final rule will become effective for episodes that begin on or after January 1, 2015. Although we are eliminating the narrative requirement prospectively, the narrative requirement continues to apply to services furnished during episodes that begin before January 1, 2015.

Comment: One commenter stated that for claims currently undergoing retrospective review, CMS should find HHAs ''without fault'' under 42 U.S.C. 1395gg and section 1870 of the Act in receiving payments where the physician has provided the narrative, although perhaps not sufficient, in addition to meeting all other certification requirements. In finding the HHAs ''without fault'' CMS would simply be acknowledging that the nature of the earlier face-to-face guidance could lead to a provider acting in good faith in submitting a claim that might not meet the documentation standards. One commenter stated that CMS should issue clarifying guidance, to be applied to claims currently being reviewed, that explains what constitutes a compliant or sufficient narrative.

Response: Providers are required to submit documentation adequate to justify payment under Medicare. Where we deny a claim due to insufficient documentation of the face-to-face encounter, we are also inherently determining that the provider is not without fault because the provider has not met its burden to submit documentation adequate to justify payment. The Medicare Financial Management Manual addresses the ''without fault'' clause of section 1395gg of the Act and states that a provider is not without fault if it fails to provide the documentation necessary to determine that the billed-for services are covered.[8] We believe that we have provided sufficient education and guidance to providers on the requirements for sufficiently documenting the face-to-face encounter as part of the certification of eligibility.

CMS has issued several educational articles and a set of Q&As to help aide physicians and HHAs in complying with the face-to-face encounter narrative requirement. The most recent article issued—MLN Matters® SE1405: Documentation Requirements for Home Health Prospective Payment System (HH PPS) Face-to-Face Encounter—explains what constitutes a sufficient face-to-face encounter narrative and includes several examples. Other articles and a set of Q&As on the face-to-face encounter requirement and physician certification of eligibility can be found on the Home Health Agency (HHA) center Web page at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* under ''spotlights''.

Comment: Several commenters stated that CMS should educate its contractors to ensure that there are consistent and standardized audit practices. Other commenters stated that if CMS reviews the certifying physician's and/or facility's medical record for the patient, CMS should adequately prepare physicians to implement this new policy by educating physicians on the requirements for home health eligibility, how to sufficiently document patient eligibility, and the Medicare definition of confined to the home.

Response: We use several methods to ensure consistency in medical reviews, including contractor oversight and the use of inter-rater reliability to ensure that all reviewers are interpreting the policy the same. We offer a range of educational resources through online manuals and Web site postings for HHAs and physicians who order these services. When appropriate, we also provide direct guidance and education to Medicare providers and suppliers. We encourage HHAs to work with their designated MAC to address any issues that arise in the claims payment process. We agree with commenters who suggested that we educate physicians regarding any policy changes finalized in this final rule and provide general education to physicians on certifying beneficiaries for Medicare home health services. We will do so via,

[7] Medicare Benefit Policy Manual, (CMS Pub. 100–02), Ch. 7, sec. 40.1.2.2. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

[8] Medicare Financial Management Manual, (CMS Pub. 100–06), Ch. 3, sec. 90.1(E). Available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/fin106c03.pdf*

for example, open door forums, email listserv announcements, and MedLearn articles.

Comment: A few commenters stated that the certifying physician would not have, nor should be required to have, sufficient documentation within his/her medical record for the patient to support his/her certification that the patient is eligible for the Medicare home health benefit. Several commenters stated that HHAs should not be liable for documentation errors made by physicians, whom they have little direct control over and some commenters stated that it is neither reasonable for the HHA to obtain all the documentation needed from the certifying physician and/or the acute/post-acute care facility that may have been used to certify patient eligibility and/or lead to the referral for home care. A few commenters stated that CMS' proposals to base reimbursement of one provider on documentation maintained by another, separate provider is unprecedented. Several commenters stated that if CMS begins reviewing the certifying physician's records for the patient, physician's will cease to refer patients to home health out of fear of patient record audits and frustration with administrative burden.

Response: In accordance with the statutory language at sections 1814(a)(2) and 1835(a)(2) of the Act, physicians are required to have, and thus be able to provide, material that appropriately supports their certification and recertification of Medicare home health beneficiaries, as provided by regulations. When we proposed to require a face-to-face encounter narrative, comments, which were summarized and addressed in the CY 2011 HH PPS final rule (75 FR 70431), communicated to CMS that ''the HHA has no control over the quality of the physician's documentation and no method to enforce proper physician documentation''. We stated in our response that:

''it is important to reiterate that to be eligible for Medicare's [home health] benefit, the patient must be under the care of a physician, and it is ultimately the responsibility of the HHA that this criterion is met. We have always held the HHA responsible for ensuring that there is a physician-signed plan of care, physician-signed orders, and a physician-signed certification. Therefore, we will also hold the agencies responsible for the certifying physician's encounter documentation. By statute, this documentation is a requirement for payment just as a physician-signed certification of eligibility is a requirement for payment'' (75 FR 70430).

We also stated in the CY 2011 HH PPS final rule that: ''we would expect that a physician who performs a medically necessary physician service, which also satisfies the face-to-face encounter requirement, would maintain medical record documentation concerning the encounter, and the clinical findings associated with that encounter would be consistent with the physician's certification documentation'' (75 FR 70431). While we stated that the HHA was ''held harmless'' if the certification of eligibility, including the face-to-face encounter narrative, was sufficient, we noted that the certifying physician was still expected to fulfill his or her responsibility for ensuring appropriate medical record documentation associated with the certification and/or encounter and any associated Medicare billing (75 FR 70431). Since we proposed to eliminate the face-to-face encounter narrative, with respect to which commenters were overwhelmingly supportive, the only other source that would substantiate the certification of eligibility is the certifying physician's and/or the acute/post-acute care facility's medical record for the patient.

We do not agree that requiring documentation from the certifying physician's and/or acute/post-acute care facility's medical record for the patient to substantiate the certification of eligibility is unprecedented. For any Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) item to be covered by Medicare:

''the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). . . . However, neither a physician's order nor a certificate of medical necessity (CMN) nor a DME information form (DIF) nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).'' [9]

The analysis in section III.A in this final rule shows that since the implementation of the face-to-face encounter requirement there has been little change in home health utilization. As such, we would not expect the elimination of the narrative and the review of documentation from the certifying physician's and/or post-acute/acute care facility's medical record for the patient to have a substantial impact on utilization for those beneficiaries who are truly eligible to receive services under the Medicare home health benefit. We will continue to monitor for potential impacts due to the face-to-face encounter requirements and other policy changes in the future.

Comment: Commenters were generally opposed to using only the certifying physician's and/or acute/post-acute care facility's medical record for the patient to determine initial patient eligibility for the home health benefit. Commenters generally went on to state that all medical necessity and eligibility determinations should be based on whether the full patient record, regardless of who holds it, establishes that the patient is homebound and in need of skilled care. Other commenters suggested that CMS adopt a policy that allows the certifying physician documentation that supports the certification of eligibility for home health services to be maintained in the medical record of the HHA or allow information from the HHA to be incorporated into the certifying physician's medical record for the patient. One commenter noted that when MAC and RAC reviews are conducted, it can be years after the service was actually provided and it could be difficult to obtain information from the facility/certifying physician years later as the medical record for the patient may have been moved off-site for storage.

Response: In accordance with the statutory language at sections 1814(a)(2) and 1835(a)(2) of the Act, a physician is required to certify and re-certify the patient's eligibility for the home health benefit. This is also a condition for Medicare payment per the regulations at § 424.22. Without a valid certification/re-certification of eligibility, there can be no payment made to the HHA. Section 1833(e) of the Act further states that: ''No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.'' Similarly, section 1815(a) of the Act states that: ''. . . no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period

[9] Medicare Program Integrity Manual (CMS Pub. 100–08) Ch.5, sec. 5.7. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf.*

with respect to which the amounts are being paid or any prior period.'' Since the certification/re-certification of eligibility is a requirement for payment and a physician, independent from the HHA as outlined in § 424.22(d), must complete the certification/re-certification of eligibility, only the certifying physician's and/or the acute/post-acute care facility's medical record for the patient that was used as the basis for the certification of eligibility can demonstrate whether the certification/re-certification of eligibility is valid.

We agree with the suggestions made by the commenters that the certifying physician and/or acute/post-acute care facility should provide the documentation that substantiates the patient's eligibility to the HHA upon request. The HHA must provide the documentation from the certifying physician and/or acute/post-acute care facility that substantiates the patient's eligibility for the Medicare home health benefit to CMS and/or its contractors upon request. We also agree with commenters that it would be permissible for the HHA to communicate with and provide information to the certifying physician about the patient's homebound status and need for skilled care and for the certifying physician to incorporate this information into his or her medical record for the patient. However, the certifying physician must review and sign off on anything incorporated into his or her medical record for the patient that is used to support his/her certification/re-certification of patient eligibility for the home health benefit. In addition, any information from the HHA (including the comprehensive assessment) that is incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient (if the patient was directly admitted to home health) and used to support the certification of patient eligibility for the home health benefit, must corroborate the certifying physician's and/or the acute/post-acute care facility's own documentation/medical record entries, including the diagnoses and the patient's condition reported on the comprehensive assessment.

Comment: Commenters questioned how the process of reviewing the certifying physician and/or acute/post-acute care facility medical record for the patient would be operationalized. Specifically, commenters asked if medical review auditors would contact the certifying physician and/or acute/post-acute care facility directly to obtain records for review and if HHAs would be penalized if certifying physician and/or acute/post-acute care facility patient records are not readily available for review. Some commenters questioned whether medical record reviews would happen upon request, such as a MAC or RAC additional documentation request, or if the HHA would be responsible for obtaining the supporting documentation from the certifying physician and/or acute/post-acute care facility and, if so, whether the documentation should be obtained upon referral. A few commenters stated that if HHAs are responsible for securing supporting documentation, it could lead to delays in accepting patients, which in turn could lead to issues in complying with other regulations, such as the timeframe required for completing the initial assessment.

Response: After reviewing all of the public comments received, we believe that the best process is for the certifying physician and/or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health) to provide the documentation used as the basis for the certification of home health eligibility, upon request, to the home health agency, review entities, and/or CMS. The HHA will obtain the documentation from the certifying physician and/or acute/post-acute care facility that substantiates the certification of patient eligibility for its own medical record for the patient and must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided. Obtaining documentation from the certifying physician and/or acute/post-acute care facility should not lead to delays in accepting patients. We require certifications to be obtained at the time the plan of care is established or as soon thereafter as possible.[10] This allows flexibility for HHAs to develop the plan of care in consultation with the physician, if needed.

The plan of care requirements in the Medicare Conditions of Participation (CoPs) at § 484.18(a) states that the plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

The Medicare CoPs, at § 484.55(a), require the completion of an initial assessment within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date. The initial assessment visit must be done to determine the immediate care and support needs of the patient and to determine eligibility for the Medicare home health benefit, including homebound status. The Medicare CoPs, at § 484.55(b), require a comprehensive assessment to be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care, and for eligibility for the Medicare home health benefit to be determined, including homebound status. We would expect that the findings from initial assessment and/or comprehensive assessment of the patient would be communicated to the certifying physician. The certifying physician can incorporate this information into his/her medical record for the patient and use it to develop the plan of care and to support his/her certification of patient eligibility. The certifying physician must review and sign off on anything incorporated it into his or her medical record for the patient that is used to substantiate the certification/re-certification of patient eligibility for the home health benefit.

Also, per the regulations at § 424.22(a)(1)(v), the face-to-face encounter itself, can occur up to 30 days after the start of care. As such, there may be instances where the certification of patient eligibility and associated supporting documentation may not be available until after the patient has been accepted by the HHA and services have commenced. As noted above, the certification must be obtained at the time the plan of care is established or as soon thereafter as possible. Therefore, it is not acceptable for HHAs to wait until the end of the 60-day episode of care to obtain a completed certification of

[10] Medicare General Information, Entitlement, and Eligibility Manual (CMS Pub. 100–01) Ch. 4, sec. 30.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c04.pdf.*

patient eligibility and supporting documentation from the certifying physician and/or the acute/post-acute care facility (if the patient was directly admitted to home health).

Comment: Commenters stated that most of the issues with the face-to-face encounter narrative stemmed from a misunderstanding by providers and physicians on what is considered a sufficient narrative. Therefore, if the certifying physician's and/or acute/post-acute care facility's medical record for the patient is reviewed to determine initial patient eligibility for the home health benefit, then CMS should define what it would consider sufficient documentation to substantiate the certification of eligibility. Some commenters stated that it is impossible for the HHA to ensure that the documentation in the certifying physician and/or acute/post-acute care facility medical record for the patient is sufficiently detailed to support the certification of patient eligibility. A few commenters stated that some physicians are reluctant or resistant to providing additional documentation or changing previous practices in order to comply with new requirements.

Response: HHAs should obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met. As previously noted, we have issued several educational articles and a set of Q&As to help aide physicians and HHAs in complying with the face-to-face encounter narrative requirement and similarly could be used as a guide on what would be considered adequate documentation in the certifying physician's and/or acute/post-acute care facility's medical record for the patient to substantiate eligibility for the Medicare home health benefit. The most recent article issued—*MLN Matters® SE1405: Documentation Requirements for Home Health Prospective Payment System (HH PPS) Face-to-Face Encounter*—explains what constitutes a sufficient face-to-face encounter narrative and includes several examples. Other articles, including SE1405, and a set of Q&As on the face-to-face encounter requirement and physician certification of eligibility can be found on the Home Health Agency (HHA) center Web page at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* under ''spotlights''.

The Medicare Financial Management Manual requires providers to provide the documentation necessary to determine that the billed-for services are covered.[11] Home health services cannot be covered without a valid patient certification/re-certification of eligibility, in accordance with our regulations at § 424.22. The certifying physician and/or the acute/post-acute care facility medical record for the patient must contain information that justifies the referral for Medicare home health services, including the need for the skilled services initially ordered and the patient's homebound status. This information can be found most often in clinical and progress notes and discharge summaries. In addition, the certifying physician's and/or acute/post-acute care facility's medical record for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the visit occurred within the required timeframe, was related to the primary reason the patient requires home health services, and was performed by either: (1) The certifying physician; (2) a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health; or (3) an allowed NPP as set out in § 424.22(a)(1)(v)(A).

It is permissible for the HHA to communicate with and provide information to the certifying physician about the patient's homebound status and need for skilled care and for the certifying physician to incorporate this information into his or her medical record for the patient. The certifying physician must review and sign off on anything incorporated it into his or her medical record for the patient that is used to support his/her certification/re-certification of patient eligibility for the home health benefit. In addition, any information from the HHA (including the comprehensive assessment) that is incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient (if the patient was directly admitted to home health) and used to support the certification of patient eligibility for the home health benefit, must corroborate the certifying physician's and/or the acute/post-acute care facility's own documentation/medical record entries, including the diagnoses and the patient's condition reported on the comprehensive assessment. With respect to DMEPOS, it has been our longstanding policy that records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that a DMEPOS item is reasonable and necessary. We believe the same safeguards are necessary for home health patient eligibility determinations and consistent with the statutory intent in sections 1814(a), 1835(a) and 1877 of the Act, which require a physician, who does not have financial relationship with the HHA, to certify the patient's eligibility for home health services.

We want to remind certifying physicians and acute/post-acute care facilities of their responsibility to provide the medical record documentation that supports the certification of patient eligibility for the Medicare home health benefit. Certifying physicians who show patterns of non-compliance with this requirement, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews.

Comment: A few commenters questioned whether a certification statement will still be required, if the certification statement can be added to the plan of care, and what exactly constitutes a sufficient certification of eligibility. One commenter recommended that CMS consider a signed and dated order for home health services for an eligible patient by an eligible practitioner as satisfying the certification requirements.

Response: As a reminder, the statute at sections 1814(a)(2)(C) and 1835(a)(2)(A) outlines the certification and re-certification requirements for Medicare home health services. These requirements are also reflected in regulations at § 424.22(a) and (b). A physician will still be required to certify patient eligibility for the Medicare home health benefit. Specifically for a certification of eligibility to be sufficient, a physician must certify that:

- The individual needs or needed intermittent skilled nursing care, physical therapy, and/or speech-language pathology services as defined in § 409.42(c).
- Home health services are or were required because the individual was confined to the home (as defined in sections 1835(a) and 1814(a) of the Act), except when receiving outpatient services.
- A plan for furnishing the services has been established and is or will be

[11] Medicare Financial Management Manual, (CMS Pub. 100–06), Ch. 3, sec. 90.1(E). Available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/fin106c03.pdf*

periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine (a doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law).[12]

- Home health services will be or were furnished while the individual is or was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.
- A face-to-face patient encounter occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care, was related to the primary reason the patient requires home health services, and was performed by the certifying physician, a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health, or an allowed NPP defined in § 424.22(a)(1)(v). The certifying physician must also document the date of the encounter as part of the certification.

For instances where the physician orders skilled nursing visits for management and evaluation of the patient's care plan,[13] the certifying physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately after the narrative in the addendum.

When there is a continuous need for home health care after an initial 60-day episode of care, a physician is also required to recertify the patient's eligibility for the home health benefit. In accordance with § 424.22(b), a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. In recertifying the patient's eligibility for the home health benefit, the recertification must indicate the continuing need for skilled services and estimate how much longer the skilled services will be required. The need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care, physical therapy, or speech–language pathology services. Again, for instances where the physician ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately after the narrative in the addendum.

Comment: One commenter strongly believed that allowing a face-to-face encounter to occur up to 90 days prior to the start of home health care was not appropriate, stating that if a physician saw the patient 90 days ago and did not order home health care at that time, then it is unclear why is home health being ordered at a later date. Several commenters recommended that CMS eliminate the face-to-face encounter requirement altogether for instances where the patient was admitted directly from an acute/post-acute care facility since the patient would have seen a physician.

Response: We did not propose to alter the timeframes during which a face-to-face encounter can occur nor did we propose to eliminate the face-to-face requirement for instances where the patient was admitted directly from an acute/post-acute care facility. We refer the commenters to the CY 2011 HH PPS final rule (75 FR 70428–70429), where we outlined our rationale on why the face-to-face encounter timeframe of up to 90 days prior and no more than 30 days after the start of home health care was finalized. We believe that sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act do not provide the Secretary with the authority to eliminate the face-to-face encounter requirement altogether for instances where the patient was admitted directly from an acute/post-acute care facility. However, since we are finalizing the elimination of the face-to-face narrative requirement as part of the certification of eligibility for home health services, and, as commenters' noted, an encounter with a physician would have certainly occurred when a patient is admitted directly from an acute/post-acute care facility, documenting the date of the face-to-face encounter should not be burdensome. Although a home health patient would have seen a physician if they were admitted directly from an acute/post-acute care facility, the certification of eligibility still requires that the encounter be related to the primary reason for home health care. Therefore, we believe that documentation of a face-to-face encounter as part of the certification of eligibility should still be required for patients admitted into home health care directly from an acute/post-acute care facility.

Comment: Several commenters, including MedPAC, asked that CMS develop a standardized form for use in certifying patient eligibility for the home health benefit and/or making referrals to home health. MedPAC noted that CMS concurred with three recommendations in a recent audit by the Office of Inspector General (OIG), including the consideration of a standardized form for the face-to-face encounter narrative to simplify compliance. Other commenters asked that CMS consider requiring the use of CMS–485 form again.

Response: We do not believe that a standard certification/recertification of eligibility form is necessary given the elimination of the face-to-face narrative. The regulations at 42 CFR 424.22 clearly articulate what elements need to be contained in a certification/re-certification form created by an HHA. We are pursuing development of an electronic clinical template that would allow electronic health records vendors, in all 50 states, to assist physicians in thoroughly documenting patient eligibility for the Medicare home health benefit. In order to facilitate adoption of suggested clinical elements by the provider community, we are currently collaborating with the Office of the National Coordinator for Health IT (ONC) and the electronic Determination of Coverage (eDoC) workgroup in developing the interoperability standards necessary for an electronic clinical template. We do not believe that we should require the use of the old CMS–485 form. The CMS–485 form was discontinued over a decade ago to provide HHAs with more plan of care flexibility. We encourage HHAs and physicians to work together in developing formats for the home health plan of care that best meets their needs.

[12] The physician cannot have a financial relationship as defined in § 411.354 of the chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation.

[13] Skilled nursing visits for management and evaluation of the patient's care plan are reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition (reference § 409.33 and section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual (Pub. 100–02)).

Comment: We received several comments advocating for us to allow other types of clinicians to certify eligibility and order home health services, such as physician assistants, nurse practitioners, and advanced-practice registered nurses.

Response: These comments are outside the scope of this rule. We remind the commenters that the statute (sections 1814(a) and 1835(b) of the Act) require a physician to certify patient eligibility for the Medicare home health benefit. We do not have the authority to allow for someone other than a Doctor of Medicine, Osteopathy or Podiatry to certify patient eligibility for the Medicare home health benefit. A change to the statute would require an act of the Congress.

Comment: Some commenters recommended statutory changes.

Response: We remind commenters that only the Congress (not CMS) has the authority to make statutory changes.

Final Decision: We are finalizing our proposal to eliminate the face-to-face encounter narrative as part of the certification of patient eligibility for the Medicare home health benefit, effective for episodes beginning on or after January 1, 2015. The certifying physician will still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility. For instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician will still be required to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2).

In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, we will require documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be used as the basis for certification of home health eligibility. We will require the documentation to be provided upon request to the home health agency, review entities, and/or CMS. Criteria for patient eligibility are described at § 424.22(a)(1) and § 424.22(b). HHAs should obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met and must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

Again, we want to remind certifying physicians and acute/post-acute care facilities of their responsibility to provide the medical record documentation that supports the certification of patient eligibility for the Medicare home health benefit. Certifying physicians who show patterns of non-compliance with this requirement, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews.

The following is a summary of the comments we received regarding the proposal to non-cover physician claims for certification/re-certification of patient eligibility for Medicare home health services when the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit.

Comments: A few commenters appreciated the proposal to non-cover physician claims for certification/re-certification of patient eligibility for Medicare-covered home health services when the HHA claim itself was non-covered because the certification/ recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. Commenters who supported this proposal thanked CMS for linking physician billing to HHA billing as a first step in encouraging more physician accountability.

Response: We thank the commenters for their support. We agree that this is an important first step in reminding physicians that coordination and collaboration between the physician and the HHA is essential in providing quality patient care. Coordination and collaboration should include sharing pertinent patient information with one another, especially with regard to the patient's skilled needs and homebound status. Both entities—the physician who is ultimately responsible for the patient while he/she is receiving home health services and the HHA providing such services—should be held accountable and compensated for their services when appropriate.

Comment: Most commenters generally disagreed with the proposal to non-cover physician claims for certification/ re-certification of patient eligibility for Medicare home health services when the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. One commenter questioned how CMS will identify ''Part B claims for certification/re-certification'' and stated that the face-to-face encounter visit could occur during one of several Evaluation & Management (E&M) visits. Several commenters stated that while they support encouraging physicians to engage in the planning and oversight of home health services, they are concerned that some physicians, with limited understanding of the regulations, may be reluctant to refer to home health because of concerns about denials of reimbursement. Other commenters stated that physician claims for certification/recertification should not be denied because physicians are ''in good faith'' certifying the patient's eligibility for the home health benefit and billing for certification/ recertification also includes activities performed to ensure the initial implementation of the plan of care. A few commenters suggested that, at a minimum, finalizing this proposal should be delayed until it can be proposed as part of the annual changes to the physician fee schedule.

Response: Physician certification or re-certification claims are Part B physician claims paid for under the Physician Fee Schedule. These claims are claims billed using HCPCS code G0180 (certification) or G0179 (re-certification). These claims are not Evaluation and Management claims and are billed when the patient is not present. The descriptions of these two codes indicate that they are used to bill for certification or re-certification of patient eligibility ''*for Medicare-covered* home health services under a home health plan of care (patient not present), including contacts with home health

agency and review of reports of patient status required by physicians to affirm the initial implementation of the plan of care that meets patient's needs, per certification period.'' As underlined above, we note that these codes are for physician certification or re-certification for Medicare-covered home health services. If there are no Medicare-covered home health services, these codes should not be billed or paid. As such, if the HHA claim is denied, the corresponding physician claim should not be covered because there is no longer a corresponding claim for Medicare-covered home health services. Physicians still have the option of billing Part B for E&M visits provided, transition care management, and other services as long as they follow the required billing instructions. We believe that including this proposal in the CY 2015 HH PPS proposal rule is sufficient and there is no need to re-propose this policy in next year's Physician Fee Schedule proposed rule. We received over 300 comments on the CY 2015 HH PPS proposed rule, many of which were from physician associations, such as the American College of Physicians, American Academy of Home Care Medicine, American Medical Association, and the Society of Hospital Medicine, among others.

Comment: Commenters stated that non-coverage of physician claims for certification/re-certification when the HHA claim itself was non-covered would most likely not result in a change in physician practices/behaviors due to the small payment amounts for such claims. HHAs will still encounter issues with obtaining the necessary certification/re-recertification and supporting documentation form the certifying physician.

Response: While the non-coverage of physician claims for certification/re-certification of patient eligibility for Medicare-covered home health services following the denial of a HHA claim may not serve as a sufficient incentive for encouraging certifying physicians to work collaboratively with HHAs and to provide the necessary documentation to substantiate the certification of eligibility, certifying physicians who show patterns of non-compliance with providing sufficient documentation, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews. Claims subject to increased review may include services unrelated to the home health claim being reviewed or the beneficiary who was referred for home health services.

Final Decision: We are finalizing this proposal as proposed. Physician claims for certification/recertification of eligibility for home health services (G0180 and G0179, respectively) will not be covered if the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. This proposal will be implemented through future sub-regulatory guidance.

3. Proposed Clarification on When Documentation of a Face-to-Face Encounter Is Required

In the CY 2011 HH PPS final rule (75 FR 70372), in response to a commenter who asked whether the face-to-face encounter is required only for the first episode, we stated that the Congress enacted the face-to-face encounter requirement to apply to the physician's certification, not recertifications. In sub-regulatory guidance (face-to-face encounter Q&As on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf*), response to Q&A #11 states that the face-to-face encounter requirement applies to ''initial episodes'' (the first in a series of episodes separated by no more than a 60-day gap). The distinction between what is considered a certification (versus a recertification) and what is considered an initial episode is important in determining whether the face-to-face encounter requirement is applicable.

Recent inquiries question whether the face-to-face encounter requirement applies to situations where the beneficiary was discharged from home health with goals met/no expectation of return to home health care and readmitted to home health less than 60 days later. In this situation, the second episode will be considered a certification, not a recertification, because the HHA will be required to complete a new Start of Care (SOC) OASIS to initiate care. However, for payment purposes, the second episode is considered a subsequent episode, because there was no gap of 60 days or more between the first and second episodes of care. Therefore, in order to determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, we proposed to clarify that the face-to-face encounter requirement is applicable for certifications (not recertifications), rather than initial episodes. A certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care. Because we proposed to clarify that a certification is considered to be any time that a new SOC OASIS is completed to initiate care, we will also revise Q&A #11 on the CMS Web site (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf*) to reflect this proposed clarification. If a patient was transferred to the hospital and remained in the hospital after day 61 (or after the first day of the next certification period), once the patient returns home, a new SOC OASIS must be completed. Therefore, this new episode will not be considered continuous and a face-to-face encounter needs to be documented as part of the certification of patient eligibility.[14]

Comment: One commenter stated that they were confused by the proposal and were seeking clarification as to whether CMS was proposing to require documentation of a face-to-face encounter for all certification episodes, initial and re-certifications.

Response: We are not requiring documentation of a face-to-face encounter for all certification periods. Documentation of a face-to-face encounter is only required for certifications and not re-certifications. As previously noted, a certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care. A recertification is any second or later episode of continuous home health care (where a recertification/follow-up OASIS is completed).[15]

Comment: A few commenters were supportive of the proposed clarification on when documentation of a face-to-face encounter is required. One commenter stated that their agency has been obtaining these since the inception of the face-to-face requirement and that the

[14] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/downloads/OASISConsiderationsforPPS.pdf*

[15] We note that for instances where the patient was hospitalized and then returns to home health during the last 5 days of an episode of care, the requirement to complete a resumption of care OASIS could overlap with the time period requiring completion of a recertification/follow-up OASIS. In these instances, only the resumption of care OASIS is necessary and the subsequent episode of care would still be considered ''continuous'' and thus require a re-certification of patient eligibility. If the patient receives a re-certification assessment during days 56–60, is hospitalized, and returns home *on* day 61 following, if the HHRG remains the same then the second episode of care would be considered continuous and thus be considered a re-certification. However, if the HHRG is different, this would result in a new Start of Care (SOC) OASIS and thus be considered a new certification.

proposed clarification would not present a change. The commenter goes on to state that the proposed clarification helps to ensure that the patient continues to have real oversight from the community physician that is overseeing the patient's care.

Response: We thank the commenters for their support of the proposed clarification. We have heard, anecdotally, from several HHAs that they are already in compliance with this proposed clarification and, as such, this clarification will pose no additional burden for those HHAs. We agree that equating a certification with any time a SOC OASIS is completed to initiate care will further encourage physician accountability in certifying a patient's eligibility for the Medicare home health benefit and in establishing and overseeing the patient's plan of care.

Comment: Several other commenters focused their comments solely on instances where a patient was discharged and then readmitted during the same 60-day episode of care. Commenters stated that CMS should not finalize its proposal as these episodes are currently subject to partial episode payment (PEP) adjustments and that the PEP adjustment is an appropriate safeguard to prevent inappropriate utilization. A few commenters asked CMS to clarify whether instances where the patient is returning to home health post-discharge with care initiated with a new SOC OASIS, but during (what would have been) the same 60-day episode of care, would require documentation of a new physician face-to-face encounter. A few commenters expressed concerns with the current PEP policy and stated that some HHAs are not discharging patients that have finished their course of treatment so that those episodes will not become PEPs if the patient is discharged and returns to home care within (what would have been) the 60-day episode of care.

Response: A Partial Episode Payment (PEP) is applied to home health episodes that either end in discharge and are then followed by readmission to the same home health agency (HHA) within (what would have been) the original 60-day episode, or result in a transfer to a HHA that is different than the HHA that provided the initial home health episode. The purpose of this clarification is to ensure that HHAs understand when they must document that a face-to-face encounter occurred. For instances where a patient was discharged and then readmitted during (what would have been) the same 60-day episode of care, the second episode would be considered a certification as it would be initiated with a SOC OASIS and would require documentation of a face-to-face encounter. Depending on when the face-to-face encounter occurred, the face-to-face encounter from the PEP episode could be used for the new certification as long as it was performed within the required timeframe and is still related to the primary reason the patient requires home health services. The average number of days between a PEP episode and a subsequent episode of care was 17.5 days, with the 25th percentile at 5 days and the 75th percentile at 24 days in CY 2012 and approximately 60 percent of the time there was a hospitalization between a PEP episode and the subsequent episode of care. For those instances where the patient was hospitalized between the PEP episode and the subsequent episode of care, the patient would have seen a physician, so documenting the face-to-face encounter as part of the certification of eligibility for the subsequent episode of care should be easily accomplished.

PEP episodes are paid a rate which is proportional to the days of service provided during the episode. In CY 2012 only 2.2 percent of episodes were PEP episodes. Table 9 below compares the number of days in between the last visit and the ''through'' date on the claim for PEPs and Non-PEP episodes. The distribution below for non-PEP episodes does not indicate that there is a wide-spread issue with HHAs refusing to discharge patients that have otherwise met all goals long before the end of the 60-day episode in hopes of avoiding PEPs. However, we will continue to monitor PEP episodes and will consider whether a refinement to the PEP policy is necessary in the future.

TABLE 9—DISTRIBUTION OF DAYS BETWEEN THE LAST EPISODE VISIT AND EPISODE THROUGH DATE FOR NON-PEP EPISODES (N = 3,796,143) AND PEP EPISODES (8,105) AT LEAST 55 DAYS IN LENGTH, CY 2012

Distribution point	*Non-PEP episodes*	*PEP Episodes*
10th Percentile ..	1.0	1.0
25th Percentile ..	1.0	1.0
50th Percentile (Median)	2.0	1.0
Mean Average ..	4.7	6.9
75th Percentile ..	4.0	7.0
90th Percentile ..	7.0	24.0
99th Percentile ..	52.0	51.0

Source: Abt Associates analysis of 100% CY 2012 Medicare Home Health claims data.

Comment: One commenter asked that CMS confirm that over 800,000 episodes fit into a category of admissions shortly following discharges with goals met because that number seemed high.

Response: In the CY 2015 HH PPS proposed rule we noted, in the Collection of Information section, that: ''we estimate that of the 6,562,856 episodes in the CY 2012 home health Datalink file, 3,096,680 SOC assessments were performed on initial home health episodes. If this proposal is implemented, an additional 830,287 episodes would require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new SOC OASIS assessment'' (79 FR 38412). This includes instances where patients finished a 60-day episode of care, were discharged, and then were re-admitted before 60 days lapsed without having home health care. In addition, this estimate represents a ''worst-case'' scenario as it does not account for instances where HHAs already consider anytime a new SOC OASIS is completed as a certification and are thus already in compliance. Home Health Compare, via Medicare.gov, reports national and state-level data on how often home health patients had to be admitted to the hospital and how often patients receiving home health care needed urgent, unplanned care in the ER without being admitted. Nationally, for CY 2013, 12 percent of home health patients receiving home health care needed urgent, unplanned care in the emergency room and 16 percent of home health patients had to be admitted to the hospital. Subsequent episodes initiated with a SOC OASIS represent 12.7 percent of all home health episodes in the CY 2012 Datalink file. Most commenters focused on instances where the initial episode of care was a PEP (that is, the patient transferred to another HHA or was discharged before the end of a 60-day episode and then re-admitted during what would have been the same 60-day episode of care), which were only 2.2 percent of episodes in CY 2012.

This clarification was intended to mostly respond to instances of patients being discharged after the end of a 60-day episode of care and then re-admitted without a 60-day gap in care before the start of the next episode. For claims processing purposes (to categorize episodes into ''early'' versus ''late'' for case-mix adjustment), these episodes are considered subsequent episodes rather than initial episodes of care. Sub-regulatory guidance (face-to-face encounter Q&As on the CMS Web site at: *http://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf) stated that face-to-face encounter requirement applies to ''initial episodes''. We received several questions from the MACs and providers asking whether the face-to-face encounter was required for instances where the patient was discharged at the end of a 60-day episode of care and then re-admitted, sometimes up to 50 days later and for reasons completely unrelated to the previous episode of care. This prompted us to propose a clarification in the CY 2015 HH PPS proposed rule that would make it clear that documentation of a face-to-face encounter is required for each certification and a certification is any time a SOC OASIS is completed to initiate care.

Comment: One commenter stated that while it is understandable to categorize the completion of a SOC OASIS as a certification, thus requiring documentation of a face-to-face encounter, concerns exist that this will increase burden without any direct benefit. Several commenters stated that for subsequent episodes initiated with a SOC OASIS, a certification (which requires documentation of a face-to-face encounter) versus a recertification should be differentiated based on whether the reason for home care changed. Several commenters stated that a new face-to-face encounter should only be required when the second admission to home health services is for a wholly different reason than presented in the original admission. One commenter stated that a subsequent episode should only be considered a certification (which requires documentation of a face-to-face encounter) when a new physician is the certifying physician or if a new home health agency is providing the care.

Response: If the patient is hospitalized during a 60-day episode of care and is expected to return to home health during the same 60-day episode of care, the HHA has the option to complete a transfer OASIS without discharging the patient. If the patient returns to home heath during that same 60-day home health episode, a resumption of care OASIS would be completed upon return, and depending on when the patient returned to home health, a re-certification/follow-up OASIS would be completed during the last 5 days of the episode. The subsequent episode would be considered continuous for re-certification purposes and documentation of a face-to-face encounter would not be required. More often than not, the primary reason for home care is changing between episodes of care when the subsequent episode of care is initiated with a SOC OASIS, regardless of whether the patient remains with the same HHA or is receiving care from another HHA. As such, we are clarifying that documentation that face-to-face encounter occurred is required for every certification and that a certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care.

When comparing the primary reason for home health care (the primary diagnosis (item M1020) on the OASIS) at the ICD–9–CM three-digit category level, subsequent episodes initiated with a SOC OASIS had a different primary diagnosis (primary reason for home care) than the previous episode of care approximately 73 percent of the time. The subsequent episode's primary diagnosis was different from the previous episodes' primary diagnosis approximately 70 percent of the time when the subsequent episode of care was with the same HHA, and 80 percent of the time when the subsequent episode of care with a different HHA. Just examining the subsequent episodes of care that follow a PEP, we found that subsequent episodes of care initiated with a SOC OASIS had a different primary diagnosis than the previous episode of care approximately 72 percent of the time. The subsequent episode's primary diagnosis was different from the previous PEP episodes' primary diagnosis approximately 66 percent of the time when the subsequent episode of care was with the same HHA, and 76 percent of the time when the subsequent episode of care with a different HHA.

As we noted above, for CY 2012, approximately 60 percent of the time there was a hospitalization between a PEP episode and the subsequent episode of care. Therefore, we determined whether there was an intervening hospitalization between the PEP episode and the episode that follows (observed in the 60 days prior to the subsequent episode's start) and if so, whether there were differences in the clinical and functional levels between the PEP episode and the subsequent episode of care (Table 10 and Table 11 below). Overall, clinical levels only matched in 53 percent of instances. Functional levels matched in 63 percent of instances. Clinical levels are higher in 24 percent of the episodes that follow PEP episodes and lower in 22 percent of episodes. Functional levels are higher in approximately 20 percent of episodes that follow PEP episodes and lower in 17 percent of episodes.

TABLE 10—CROSS-TABULATION OF CLINICAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Low	12.3%	7.1%	5.4%	9.2%	6.9%	5.1%
Medium	7.8%	12.2%	11.4%	6.7%	12.8%	12.7%
High	4.8%	9.8%	29.1%	4.1%	10.8%	31.7%

Source: Abt Associates analysis of 100% Medicare Home Health claims, CY 2012.
Note(s): Low = Clinical level 1; Medium = Clinical level 2; High = Clinical level 3 as described in section III.C of this rule.

TABLE 11—CROSS-TABULATION OF FUNCTIONAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Low	6.6%	7.8%	1.4%	6.4%	8.4%	1.4%

TABLE 11—CROSS-TABULATION OF FUNCTIONAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012—Continued

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Medium	6.9%	38.6%	10.3%	8.3%	40.6%	10.4%
High	1.1%	8.5%	18.8%	1.0%	8.1%	15.3%

Source: Abt Associates analysis of 100% Medicare Home Health claims, CY 2012.
Note(s): Low = Functional level 1; Medium = Functional level 2; High = Functional level 3 as described in section III.C of this rule.

Final Decision: In order to determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, we are clarifying that the face-to-face encounter requirement is applicable for certifications (not re-certifications), rather than initial episodes. A certification (versus recertification) is considered to be any time that a new Start of Care OASIS is completed to initiate care.

C. Recalibration of the HH PPS Case-Mix Weights

As stated in the CY 2015 proposed rule, for CY 2012, we removed two hypertension codes from our case-mix system and recalibrated the case-mix weights in a budget neutral manner. When recalibrating the case-mix weights for the CY 2012 HH PPS final rule, we used CY 2005 data in the four-equation model used to determine the clinical and functional points for a home health episode and CY 2007 data in the payment regression model used to determine the case-mix weights. We estimated the coefficients for the variables in the four-equation model using CY 2005 data to maintain the same variables we used for CY 2008 when we implemented the four-equation model, thus minimizing substantial changes. Due to a noticeable shift in the number of therapy visits provided as a result of the 2008 refinements, at the time, we decided to use CY 2007 data in the payment regression. As part of the CY 2012 recalibration, we lowered the high therapy weights and raised the low or no therapy weights to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes (March 2011 MedPAC Report to the Congress: Medicare Payment Policy, p. 176). These adjustments better aligned the case-mix weights with episode costs estimated from cost report data. The CY 2012 recalibration, itself, was implemented in a budget neutral manner. However, we noted that in the CY 2012 HH PPS final rule, we also finalized a 3.79 percent reduction to payments in CY 2012 and a 1.32 percent reduction for CY 2013 to account for the nominal case-mix growth identified through CY 2009.

For CY 2014, as part of the rebasing effort mandated by the Affordable Care Act, we reset the case-mix weights, lowering the average case-mix weight to 1.0000. To lower the case-mix weights to 1.0000, each case-mix weight was decreased by the same factor (1.3464), thereby maintaining the same relative values between the weights. This ''resetting'' of the case-mix weights was done in a budget neutral manner, inflating the national, standardized 60-day episode rate as the starting point for rebasing by the same factor (1.3464) that was used to decrease the weights. In the CY 2014 HH PPS final rule, we also finalized reductions ($80.95) to the national, standardized 60-day episode payment amount each year from CY 2014 through CY 2017 to better align payments with costs (78 FR 72293), as required by the Affordable Care Act.

For CY 2015, we proposed to recalibrate the case-mix weights, adjusting the weights relative to one another, using more current data and aligning payments with current utilization data in a budget neutral manner. We also proposed to recalibrate the case-mix weights annually in subsequent payment updates based on the methodology finalized in the 2008 refinements (72 FR 25359–25392) and the CY 2012 HH PPS final rule (76 FR 68526), with minor changes as described below. To generate the CY 2015 case-mix weights, we used CY 2013 home health claims data (as of June 30, 2014) and used the same methodology finalized in the CY 2012 HH PPS final rule, except where noted below. Similar to the CY 2012 recalibration, some exclusion criteria were applied to the CY 2013 home health claims data used to generate the CY 2015 case-mix weights. Specifically, we excluded Request for Anticipated Payment (RAP) claims, claims without a matched OASIS, claims where total minutes equal 0, claims where the payment amount equals 0, claims where paid days equal 0, claims where covered visits equal 0, and claims without a HIPPS code. In addition, the episodes used in the recalibration were normal episodes. PEP, LUPA, outlier, and capped outlier (that is, episodes that are paid as normal episodes, but would have been outliers had the HHA not reached the outlier cap) episodes were dropped from the data file.[16] We note that for the CY 2015 recalibration, a 100 percent sample of CY 2013 claims data as of June 30, 2014 with linked OASIS data was used.[17]

Similar to the CY 2012 recalibration, the first step in the CY 2015 recalibration was to re-estimate the four-equation model used to determine the clinical and functional points for an episode. The dependent variable for the CY 2015 recalibration is the same as the CY 2012 recalibration, wage-weighted minutes of care. The wage-weighted minutes of care are determined using the CY 2012 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim.[18]

The CY 2012 four-equation model contained the same variables and restrictions as the four-equation model used in the CY 2008 refinements (*http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Coleman_Final_April_2008.pdf*). The CY 2012 model was estimated using CY 2005 data, same data used in the CY 2008 refinements, thereby minimizing changes in the points for the CY 2012 four-equation model. For the CY 2015 four-equation model, we re-examined all of the four-equation or ''leg'' variables for each of the 51 grouper variables in the CY 2008 model. Therefore, a grouper variable that may have dropped out of the model

[16] At a later point, when normalizing the weights, PEP episodes are included in the analysis.

[17] Note, for the last recalibration (CY 2012 recalibration), only a 20 percent sample of data was used.

[18] Note, wage information for sub-disciplines is also used (e.g., RNs versus RNs and LPNs combined).

in one of the four equations in CY 2008 may be in the CY 2015 four-equation model and vice versa. Furthermore, the specific therapy indicator variables that were in the CY 2012 four-equation model were dropped in the CY 2015 four-equation model so that the number of therapy visits provided had less of an impact on the process used to create the case-mix weights.

The steps used to estimate the four-equation model are similar to the steps used in the CY 2008 refinements. They are as follows: [19]

(1) We estimated a regression model where the dependent variable is wage-weighted minutes of care. Independent variables were indicators for which equation or ''leg'' the episode is in. The four legs of the model are leg 1: early episodes 0–13 therapy visits, leg 2: early episodes 14+ therapy visits, leg 3: Later episodes 0–13 therapy visits, and leg 4: later episodes 14+ therapy visits.[20]Also, independent variables for each of the 51 grouper variables for each leg of the model are included.

(2) Once the four-equation model is estimated, we drop all grouper variables with a coefficient less than 5. We re-estimate the model and continue to drop variables and re-estimate until there are no grouper variables with a coefficient of 5 or less.

(3) Taking the final iteration of the model in the previous step, we drop all grouper variables with a p-value greater than 0.10. We then re-estimate the model.

(4) Taking the model in the previous step, we begin to apply restrictions to certain coefficients. Within a grouper variable we first look across the coefficients for leg1 and leg3. We performed an equality test on those coefficients. If the coefficients are not significantly different from one another (using a p-value of 0.05), we set a restriction for that grouper variable such that the coefficients are equal across leg1 and leg3. We run these tests for all grouper variables for leg1 and leg3. We also run these tests for all grouper variables for leg2 and leg4.[21] After all restrictions are set, we re-run the regression again taking those restrictions into account.

(5) Taking the model from step 4, we drop variables that have a coefficient less than 5 and re-estimate the model a final time. Using complete 2013 claims data as of June 30, 2014, there were no grouper variables with a negative coefficient at this step.

The results from the final four-equation model are used to determine the clinical and functional points for an episode and place episodes in the different clinical and functional levels. We take the coefficients from the four equation model, divide them by 10, and round to the nearest integer to determine the points associated with each variable. The points for each of the grouper variables for each leg of the model, updated with complete CY 2013 data as of June 30, 2014, are shown in Table 12. 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.

[19] All the regressions mentioned in steps 1–4 are estimated with robust standard errors clustered at the beneficiary ID level. This is to account for beneficiaries appearing in the data multiple times. When that occurs, the standard errors can be correlated causing the p-value to be biased downward. Clustered standard errors account for that bias.

[20] Early episodes are defined as the 1st or 2nd episode in a sequence of adjacent covered episodes. Later episodes are defined as the 3rd episode and beyond in a sequence of adjacent covered episodes. Episodes are considered to be adjacent if they are separated by no more than a 60-day period between claims.

[21] In the CY 2008 rule, there was a further step taken to determine if the coefficients of a grouper variable are equal across all 4 legs. This step was not taken at this time.

TABLE 12: Case-Mix Adjustment Variables and Scores

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
CLINICAL DIMENSION					
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders		6		3
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms		8		8
4	Primary Diagnosis = Diabetes		8		7
5	Other Diagnosis = Diabetes	1			
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	2	16	1	9
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)	2	7		7
8	Primary or Other Diagnosis = Gastrointestinal disorders				
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2		6		
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			
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	3	11	6	11
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
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	7	1	7
15	Primary or Other Diagnosis = Neuro 3 – Stroke	3	10	2	
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3		4		8
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	8	7	13
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	8	1	8	4
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)	4	3	2	
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				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
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	4	21	8	19
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	6	15	7	15
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications ***OR*** Skin 2 – Ulcers and other skin conditions ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	4		1	
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	2	17	8	17
29	Primary or Other Diagnosis = Tracheostomy	4	19	4	11
30	Primary or Other Diagnosis = Urostomy/Cystostomy		19		14
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)		18	6	18
32	M1030 (Therapy at home) = 3 (Enteral)		15		7
33	M1200 (Vision) = 1 or more				
34	M1242 (Pain)= 3 or 4	2		1	
35	M1308 = Two or more pressure ulcers at stage 3 or 4	4	5	4	13
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	3	19	7	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	8	33	12	26
38	M1334 (Stasis ulcer status)= 2	4	13	8	22
39	M1334 (Stasis ulcer status)= 3	7	18	10	18
40	M1342 (Surgical wound status)= 2	1	7	6	14
41	M1342 (Surgical wound status)= 3		6	5	11
42	M1400 (Dyspnea) = 2, 3, or 4		2		3
43	M1620 (Bowel Incontinence) = 2 to 5		4		3
44	M1630 (Ostomy)= 1 or 2	4	11	3	11
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	2		2	
47	M1830 (Bathing) = 2 or more	6	3	5	

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
48	M1840 (Toilet transferring) = 2 or more	1	3		3
49	M1850 (Transferring) = 2 or more	3	4	2	1
50	M1860 (Ambulation) = 1, 2 or 3	7		3	
51	M1860 (Ambulation) = 4 or more	7	8	6	8

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with SCIC or PEP adjustments were excluded.

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

Please see Medicare Home Health Diagnosis Coding guidance at http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp for definitions of primary and secondary diagnoses.

In updating the four-equation model with 2013 data (the last update to the four-equation model used 2005 data), there were a number of changes to the point values for the variables in the four-equation model. These changes reflect the change in the relationship between the grouper variables and resource use since 2005. The CY 2015 four-equation model resulted in 124 point-giving variables being used in the model (as compared to the 164 variables for the 2012 recalibration). There were 21 variables that were added to the model and 63 variables that were dropped from the model due to the absence of additional resources associated with the variable. The points for 57 variables increased in the CY 2015 four-equation model and the points for 25 variables in decreased in the CY 2015 four-equation model. There were 17 variables with the same point values.

Since there were a number of changes to the point values associated with the four-equation model, we are redefining the clinical and functional thresholds so that they would be reflective of the new points associated with the CY 2015 four-equation model. Specifically, after estimating the points for each of the variables and summing the clinical and functional points for each episode, we looked 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

Similar to the methodology used in the CY 2008 refinements, we then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[22] Also, we looked at the average resource use associated with each clinical and functional score and used that to guide where we placed our thresholds. We tried to group scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off of the CY 2015 four-equation model, points are shown in Table 13.

[22] For Step 1, 55% of episodes were in the medium functional level (All with score 15).

For Step 2.1, 60.7% of episodes were in the low functional level (Most with score 3, some with score 0).

For Step 2.2, 58.3% of episodes were in the low functional level (All with score 0).

For Step 3, 52.1% of episodes were in the medium functional level (all with score 10).

For Step 4, 41.7% of episodes were in the medium functional level (almost all with score 3).

TABLE 13: CY 2015 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
Equation(s) used to calculate points: (see Table 12)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0	0 to 5	0 to 3
	C2	2 to 3	2 to 7	1	6 to 12	4 to 16
	C3	4+	8+	2+	13+	17+
Functional	F1	0 to 14	0 to 3	0 to 9	0	0 to 2
	F2	15	4 to 13	10	1 to 7	3 to 5
	F3	16+	14+	11+	8+	6+

Once the thresholds were determined and each episode was assigned a clinical and functional level, the payment regression was estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model were 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 14 shows the regression coefficients for the variables in the payment regression model updated with complete CY 2013 data. The R-squared value for the payment regression model is 0.4680 (an increase from 0.3769 for the CY 2012 recalibration).

TABLE 14—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Medium	$24.36
Step 1, Clinical Score High	61.06
Step 1, Functional Score Medium	81.65
Step 1, Functional Score High	121.95
Step 2.1, Clinical Score Medium	56.47
Step 2.1, Clinical Score High	177.00
Step 2.1, Functional Score Medium	26.09
Step 2.1, Functional Score High	91.13
Step 2.2, Clinical Score Medium	91.83
Step 2.2, Clinical Score High	206.75
Step 2.2, Functional Score Medium	6.22
Step 2.2, Functional Score High	88.98
Step 3, Clinical Score Medium	11.00
Step 3, Clinical Score High	89.06
Step 3, Functional Score Medium	50.88
Step 3, Functional Score High	86.69
Step 4, Clinical Score Medium	74.96
Step 4, Clinical Score High	241.95
Step 4, Functional Score Medium	35.12
Step 4, Functional Score High	91.41
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	447.08
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	456.36
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−65.98
Step 4, All Episodes, 20+ Therapy Visits	872.95
Intercept	378.43

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment.

The method used to derive the CY 2015 case-mix weights from the payment regression model coefficients is the same as the method used to derive the CY 2012 case-mix weights. This method is described below.

(1) We used the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divided 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 was 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.

(2) The weights associated with 0 to 5 therapy visits were then increased by 3.75 percent, the weights associated with 14–15 therapy visits were decreased by 2.5 percent, and the weights associated with 20+ therapy visits were decreased by 5 percent. These adjustments to the case-mix weights are the same as the ones used in the CY 2012 recalibration (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes (March 2011 MedPAC Report to the Congress: Medicare Payment Policy, p. 176). These adjustments better aligned the case-mix weights with episode costs estimated from cost report data.

(3) After the adjustments in step (2) were applied to the raw weights, the weights were further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds were gradually increased. We did this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We used a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) was constant. This interpolation is the identical to the process finalized in the CY 2012 final rule (76 FR 68555).

(4) The interpolated weights were then adjusted so that the average case-mix for the weights was equal to 1.[23] This last step creates the final CY 2015 case-mix weights shown in Table 15.

[23] 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 15: CY 2015 Case-Mix Payment Weights

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5985
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7242
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8499
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9756
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1013
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.7277
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8353
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9429
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0505
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1581
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7914
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.9056
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	1.0198
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.1340
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2482
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6370
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7718
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.9066
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0413
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1761
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7662
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8829
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9996
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.1163
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2330
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.8299
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.9532
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0765
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1998
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3230
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6951
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8541
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0131
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1720
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3310
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.8242
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9651

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.1061
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.2470
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3879
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8880
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	1.0355
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1830
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.3305
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4780
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2270
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4220
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6171
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2657
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4649
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6640
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3624
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5565
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7506
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3109
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5142
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7175
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3497
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5570
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7643
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4463
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6486
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8509
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4900
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7142
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9384
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5288
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7570
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9853
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6255
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8487
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0718
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2407
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4312
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6217

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2500
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4544
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6587
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3730
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5635
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7541
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3772
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5584
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7396
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3865
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5815
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7766
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.5095
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6907
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8720
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5480
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7529
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9578
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5573
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7760
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9948
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6803
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8852
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0901
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4942
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6435
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7928
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9421
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0914
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5746
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.7097
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8448
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9798
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1149
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6313
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7796
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9280
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0763

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2246
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5116
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6847
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8578
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	1.0310
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.2041
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5920
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7509
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9098
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0687
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2276
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6487
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.8208
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9930
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.1652
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3373
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6350
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.8176
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0002
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1828
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3654
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7155
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8839
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0522
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.2206
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3889
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7721
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9538
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1354
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.3170
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4987
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.8122
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8631
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.9446
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.9208
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9717
40231	All Episodes, 20+ Therapy Visits	C2F3S1	2.0532
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1626

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.2135
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2950

To ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed to apply a case-mix budget neutrality factor to the CY 2015 national, standardized 60-day episode payment rate (see section III.D.4. of this final rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when CY 2015 case-mix weights are applied to CY 2013 utilization (claims) data to total payments when CY 2014 case-mix weights are applied to CY 2013 utilization data. This produces a final case-mix budget neutrality factor for CY 2015 of 1.0366, based on CY 2013 claims data as of June 30, 2014. The case-mix budget neutrality factor (1.0366) also takes into account the re-grouping of episodes according to the point values from the four-equation model and new clinical and functional thresholds described in section III.C, which contributes 0.0090 to the case-mix budget neutrality factor.

Section 1895(b)(3)(B)(iv) of the Act gives us the authority to implement payment reductions for nominal case-mix growth (that is, changes in case-mix that are not related to actual changes in patient characteristics over time). Previously, we accounted for nominal case-mix growth from 2000 to 2009 through case-mix reductions implemented from 2008 through 2013 (76 FR 68528–68543). In the CY 2013 HH PPS proposed rule, we stated that we found that 15.97 percent of the total case-mix change was real from 2000 to 2010 (77 FR 41553). In the CY 2014 HH PPS final rule, we used 2012 claims data to rebase payments (78 FR 72277). Since we were resetting the payment amounts with 2012 data, we did not take into account any additional nominal case-mix growth. For the proposed rule, we examined case-mix growth from CY 2012 to CY 2013 using CY 2012 and preliminary CY 2013 claims data. For this final rule, in updating our analysis with CY 2013 claims data as of June 30, 2014, we estimate that case-mix increased by 2.76 percent between CY 2012 and CY 2013. In applying the 15.97 percent estimate of real case-mix growth to the total estimated case-mix growth from CY 2012 to CY 2013 (2.76 percent), we estimate that 2.32 percent (2.76–(2.76 * 0.1597)) of the case-mix growth is nominal (that is, case-mix growth that is unrelated to changes in patient acuity).

We estimate that the case-mix budget neutrality factor of 1.0366 would have to be reduced to 1.0134 to account for nominal case-mix growth ((1.0366 − 0.0276) + (0.0276*0.1597) = 1.0134). While we considered adjusting the case-mix budget neutrality factor to take into account the growth in nominal case-mix (2.32 percent), which would result in a case-mix budget neutrality adjustment of 1.0134 rather than 1.0366, we will apply the full 1.0366 case-mix budget neutrality factor to the national, standardized 60-day episode payment rate. We will continue to monitor case-mix growth and may consider whether to propose nominal case-mix reductions in future rulemaking.

The following is a summary of the comments and our responses to comments on the CY 2015 proposed case-mix weights and methodology:

Comment: Commenters stated that CMS has not provided complete technical information on the nature and basis for the revisions to the case-mix weights and variables in the model and therefore, the recalibration of the weights cannot be sufficiently evaluated. Commenters stated that unlike previous recalibrations, CMS has not provided the technical report on the proposed recalibration of the weights and that CMS did not publish the data or the analysis used to support its conclusions. Commenters stated that a full technical report on the methodology and regression analysis would be valuable in understanding the reliability and validity of the recalibration and would allow stakeholders to conduct their own evaluations as well. A commenter recommended that CMS make all technical reports and analyses regarding the recalibration of the case-mix weights publicly available immediately in order to permit stakeholders to review the significant changes described in the proposed rule.

Response: As stated in the CY 2015 proposed rule, the methodology used to recalibrate the weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions noted in the proposed rule. We encourage commenters to refer to the CY 2012 proposed and final rule and the CY 2012 technical report on our home page at *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* for additional information about the recalibration methodology.

Comment: Commenters stated that the recalibration of the high volume therapy episodes will lead to financial incentives to increase therapy visits even though CMS has indicated that therapy visit volume should have less impact on the weights. They stated that the changes to the proposed case-mix weights contradict what was said previously regarding undervalue of clinical elements and over-value of the therapy component. Commenters presented their analyses comparing the CY 2014 weights to the CY 2015 weights and payments associated with each of the HHRGs. Commenters stated that under the CY 2015 proposed case-mix weights, a majority of the HHRGs with low therapy visits will have losses and a large number of the high therapy groups and all of the 20+ therapy episodes will receive substantial increases to their weights. Commenters stated that these results seem to contradict the adjustment discussion in the CY 2015 proposed rule.

Response: We note that the CY 2015 recalibration is based on 2013 claims data, which is six to eight years more current than the claims data used in the CY 2012 recalibration. The 2013 data also reflects the 2008 refinements to the HH PPS, which included the change from one therapy threshold to multiple therapy thresholds and the change from 80 HHRGs to 153 HHRGs. Given the time difference in the data used for the

two recalibrations, one would expect differences in the resulting case-mix weights. However, comparing the CY 2015 proposed case-mix weights to the CY 2014 final weights; we observed that over 60% of normal episodes would have a case-mix weight change of 5 percent or less. Furthermore, few episodes have an increase in their case-mix weight that exceeds 5 percent (14.2 percent) and very few episodes have an increase in their case-mix weight that exceeds 10 percent (0.4 percent).

The changes in case-mix weights can be mostly attributed to shifts in utilization patterns between 2005/2007 and 2013. Over that six to eight year time period, we find a notable shift across all therapy groups away from the use of home health aides and a shift to either more nursing or more therapy care (see Tables 16 and 17 below). While some of the low therapy groups did add more skilled nursing visits, most of the therapy groups added more occupational therapy (OT) and speech-language pathology (SLP), which have substantially higher Bureau of Labor Statistics (BLS) average hourly wage values compared to skilled nursing ($39/hr for skilled nursing versus $55 for OT and $60 for SLP).

TABLE 16—SUMMARY STATISTICS—EPISODES FROM 2013

[Only normal episodes]

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	2,951,379	8.9	2.1	0.6	0.1	0.0	0.1	0.7	11.8
6	224,325	6.0	1.3	5.2	0.6	0.1	0.1	6.0	13.3
7–9	664,911	6.5	1.5	6.9	0.9	0.2	0.2	7.9	16.0
10	184,871	6.8	1.7	8.5	1.3	0.2	0.2	10.0	18.6
11–13	532,875	7.1	2.0	10.0	1.7	0.3	0.2	12.0	21.2
14–15	249,627	7.3	2.4	11.6	2.4	0.4	0.2	14.5	24.3
16–17	267,500	6.5	2.5	13.5	2.5	0.4	0.2	16.4	25.6
18–19	173,769	7.0	2.6	13.8	4.0	0.6	0.2	18.4	28.2
20+	328,295	8.1	3.5	14.9	7.9	1.9	0.3	24.8	36.6
Total	5,577,552	7.9	2.1	5.1	1.2	0.2	0.1	6.5	16.7

Source: Data on episodes with a through date in 2013 using complete CY 2013 claims data as of June 30, 2014.

TABLE 17—SUMMARY STATISTICS—EPISODES FROM 2007 (FILE USED IN CY 2012 RECALIBRATION)

[Only normal episodes]

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
Average number of visits for Normal episodes with a through date in 2007									
0–5	520,639	9.3	3.6	0.6	0.1	0.0	0.1	0.7	13.7
6	28,349	5.5	1.7	5.3	0.6	0.1	0.2	6.0	13.4
7–9	59,156	5.9	2.1	6.9	0.9	0.1	0.2	7.9	16.1
10	47,798	7.2	2.8	8.9	1.0	0.1	0.2	10.0	20.1
11–13	107,970	7.2	3.5	10.5	1.2	0.1	0.2	11.9	22.7
14–15	38,188	7.3	4.0	12.1	2.1	0.3	0.2	14.5	25.9
16–17	29,322	7.2	4.4	13.6	2.5	0.4	0.2	16.5	28.4
18–19	17,679	7.4	4.4	14.4	3.5	0.5	0.2	18.4	30.5
20+	39,395	7.4	5.2	16.3	7.1	1.5	0.3	24.9	37.9
Total	888,496	8.3	3.5	4.7	0.9	0.1	0.1	5.7	17.7

Source: Data on episodes ending in 2007 using a 20% sample of 2007 data from the home health Datalink file.

In addition, while the average number of total visits per episode has decreased overall, it decreased disproportionately more for the no/low therapy group (which constitute over 50 percent of all episodes) compared to the remaining groups (see Table 18 below). These utilization changes result in changes to the weights observed by the commenters, specifically, the decreases in the case-mix weights for the low or no therapy groups and increases in the case-mix weights for the high therapy groups.

TABLE 18—PERCENT CHANGE IN THE AVERAGE NUMBER OF VISITS BY THERAPY GROUP, 2007 AND 2013

Therapy group	Percent change in visits from 2007 to 2013
0–5	−13.92
6	0.18
7–9	0.32
10	−7.38
11–13	−6.63
14–15	−6.14
16–17	−9.89
18–19	−7.73
20+	−3.46

We would like to clarify that the adjustments applied to the case-mix weights are not in addition to the

adjustments applied in 2012, but rather are the same adjustments as the ones applied to the 2012 data. In other words, the 3.75 percent increases to the weights associated with 0 to 5 therapy visits, the 2.5 percent decreases to the weights associated with 14–19 therapy visits, and 5 percent decreases to the weights associated with 20+ therapy visits are applied to the raw weights resulting from 2013 claims data. We did not take the CY 2012 case-mix weights and further adjust them. Therefore, one should not expect to see higher weights for low or no therapy episodes and lower weights for high therapy episodes when comparing the CY 2015 proposed case-mix weights to the CY 2014 weights, which have the same relative values as the 2012 case-mix weights.

We note that by removing the therapy indicator variables from the four equation model and moving away from the use of therapy visits in the model that the case-mix weights for high therapy groups were lower than what they would have been if the therapy indicator variables were included in the model. We also note that the final case-mix weights for the highest therapy HHRGs (those groups of episodes with 20 or more therapy visits) slightly decreased when comparing the CY 2015 final case-mix weights, based on complete CY 2013 data as of June 30, 2014, to the CY 2015 proposed case-mix weights, based on preliminary CY 2013 data as of December 31, 2013.

Comment: One commenter was supportive of the recalibration proposal and agreed that the proposed recalibration strikes an appropriate balance between discouraging inappropriate use of therapy while addressing concerns that non-therapy services are undervalued.

Response: We thank the commenter for their support.

Comment: A commenter stated that the increase in therapy visits was due to therapists providing clinically necessary skilled care, not due to manipulating the therapy reimbursement process. Another commenter questioned whether CMS utilized multiple years of OASIS data to consider the change in functional status of those patients who receive low numbers of therapy visits versus those receiving 20 or more therapy visits and if the change noted at both ends of the spectrum of therapy utilization are appropriately reflected in the recalibration effort. Another commenter stated that CMS' proposed changes do not appear to be based on any reasoned consideration of why the visit time data is the way it is.

Response: The case-mix weights are driven by the 2013 claims data with the same adjustments finalized in CY 2012 to better align payment for high and no/low therapy episodes with cost. The proposed recalibration of the case-mix weights used the methodology proposed and finalized in CY 2012, with a few noted differences outlined above and in the CY 2015 HH PPS proposed rule. We did not set the weights based on what levels of services we thought were appropriate. Any changes in the case-mix weights for CY 2015 are driven by utilization patterns observed in CY 2013 claims data.

Comment: A commenter stated that the case-mix weights appear to decrease payments for third or later episodes of care. The commenter stated that many home health providers serve patients with multiple chronic conditions and that the patients often have significant medical issues. The commenter stated that reducing payments for such episodes of care will likely have an impact on how home health providers will treat patients with chronic conditions. The commenter asked for more clarifications regarding what practice or utilization changes we are trying to achieve and if we could explain if there are particular types of patients we believe should not be receiving third episodes of home health care and/or if there are certain patients who should receive a different approach to care that would be less costly than the care delivered at present.

Response: We reiterate that CY 2015 the case-mix weights are reflective of the utilization patterns observed in the CY 2013 claims data. We have not manipulated the case-mix weights to encourage certain patterns of care for the third or later episodes. The case-mix weights are driven by the mix of services provided, the costs of services provided as determined by the BLS hourly rates, the length of the visits, and the number of visits provided. Any decreases in the case-mix weights for third or later episodes of care reflect less average resources associated with those episodes using 2013 claims data than the average resources associated with third and later episodes using 2007 data, which was the data used in the 2012 recalibration.

We note that when comparing the visit distribution in 2013 versus 2007 for third and later episodes, we observe large decreases in the total visit count in 2013 versus 2007 for these episodes (see Table 19 and Table 20). As shown in Table 21, the number of total visits for the third and later episodes, on average, decreased significantly, ranging from −8.30 percent to −19.01 percent, for the various therapy groups. The decreases in the case-mix weights for third or later episode episodes for CY 2015 versus CY 2014 may be due to the decrease in total visits for these episodes between 2007 and 2013.

TABLE 19—AVERAGE NUMBER OF VISITS FOR THIRD AND LATER EPISODES OF CARE (NOT INCLUDING 20+ THERAPY VISIT EPISODES WHICH MAY BE EARLY OR LATE), CY 2013

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	1,424,148	9.2	3.2	0.2	0.0	0.0	0.1	0.3	12.7
6	38,406	7.8	2.6	4.9	0.8	0.2	0.1	6.0	16.5
7–9	125,743	8.2	2.9	6.7	1.0	0.3	0.1	7.9	19.1
10	37,482	8.4	2.9	8.5	1.2	0.3	0.1	10.0	21.4
11–13	120,115	8.4	3.2	10.2	1.5	0.3	0.1	12.0	23.7
14–15	68,540	8.3	3.5	12.1	1.9	0.5	0.1	14.5	26.3
16–17	77,730	7.2	3.6	13.9	2.0	0.4	0.1	16.4	27.3
18–19	41,557	7.6	3.6	14.2	3.5	0.6	0.1	18.3	29.7
Total	1,933,721	8.9	3.2	2.8	0.5	0.1	0.1	3.3	15.5

Source: Data on normal episodes of care with a through date in 2013 using complete CY 2013 claims data as of June 30, 2014.

TABLE 20—AVERAGE NUMBER OF VISITS FOR THIRD AND LATER EPISODES OF CARE (NOT INCLUDING 20+ THERAPY VISIT EPISODES WHICH MAY BE EARLY OR LATE), CY 2007

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	227,934	9.6	5.9	0.2	0.0	0.0	0.1	0.2	15.7
6	3,068	7.7	4.1	5.0	0.8	0.2	0.1	6.0	18.0
7–9	7,458	8.1	4.6	6.7	1.1	0.2	0.2	8.0	20.8
10	9,510	9.0	5.2	8.7	1.1	0.2	0.1	10.0	24.3
11–13	21,620	9.0	5.8	10.4	1.3	0.2	0.1	11.9	26.8
14–15	7,736	8.6	6.4	12.4	1.8	0.3	0.1	14.5	29.6
16–17	6,481	8.2	7.0	14.1	1.9	0.4	0.1	16.5	31.8
18–19	2,982	8.8	6.7	14.9	3.0	0.5	0.2	18.4	34.0
Total	292,873	9.4	5.9	2.6	0.4	0.1	0.1	3.1	18.4

Source: Data on normal episodes of care ending in 2007 using a 20% sample of 2007 data from the home health Datalink file.

TABLE 21—PERCENT CHANGE IN THE AVERAGE NUMBER OF VISITS BY THERAPY GROUP FOR THIRD AND LATER EPISODES OF CARE, 2007 AND 2013

Therapy group	Percent change in visits from 2007 to 2013
0–5	−19.01
6	−8.38
7–9	−8.30
10	−11.75
11–13	−11.44
14–15	−11.28
16–17	−14.18
18–19	−12.72

Comment: A commenter stated that the points for the case-mix variables seem to be decreasing for the low therapy episodes and increasing for the high therapy episodes, motivating agencies to provide more therapy visits to boost reimbursement. The commenter stated that the data used to determine the case-mix points was swayed by the payment system which rewards high therapy utilization. Other commenters stated that many diagnosis codes are losing case-mix points and that there doesn't seem to be a reason behind the loss of points. Another commenter implied that there doesn't seem to be a balance in the shift in points and was concerned with the impact of the scoring variables being eliminated and others decreasing or increasing points. Another commenter stated that there is not sufficient detail to explain the Agency's rationale for the large scale changes to the case-mix point values in the proposed rule and questioned what message CMS is sending to agencies based on the changes to the case-mix variable table. The commenter stated that there is no longer an emphasis on diabetes, heart failure, COPD, or depression, but that there seems to be an emphasis on orthopedic and neurological diagnoses, particularly when 14 or more therapy visits are ordered. A commenter stated that the change in the case-mix points sends a message that there is little or no benefit to home health agencies in caring for chronically ill patients with common medical diagnoses unless those patients are receiving 14 or more therapy visits and urged CMS to reconsider adoption and implementation of the proposed case-mix point tables and new thresholds until CMS has sought more input from clinicians and agencies and has re-evaluated the messages the new case-mix table will send to the home health community.

Response: We reiterate that the points for the case-mix variables are driven by the utilization patterns observed in the CY 2013 claims data. The changes to the weights are not surprising given the different data used for the CY 2012 recalibration versus the data used for the CY 2015 recalibration. We used 2005 data to estimate the four equation model for the CY 2012 recalibration and we used 2013 data to estimate the four equation model for the CY 2015 recalibration. (The 2012 payment regression was based on a 2007 sample that was assigned to severity levels based on the point values from a 4-equation model using 2005 data that eliminated certain hypertension codes). The different point estimates across the two models indicate that the case-mix variables have a different relationship to resource use in 2013 compared to 2005. A decrease in the number of points (for 2013 compared to 2005) for a variable means that the variable is associated with less resource use on average in 2013 compared to 2005. An increase in the number of points for a variable means that the variable is associated with more resource use on average in 2013 compared to 2005. Certain variables did drop out of the 4-equation model in in the CY 2015 recalibration versus the CY 2012 recalibration. For many of those variables, the CY 2012 recalibration estimated only a small number of points associated with the variables and therefore those variables were already on the verge of being dropped from the model in CY 2012. While some variables did drop out of the model, the potential change in points associated with those variables was not very large, so that individually those variables had minimal impact on episodes' resource use. Some of the variables that dropped out of the model experienced increases in the number of episodes with the variable reported on OASIS between 2005 and 2013. The increase in episodes reporting a particular variable may have decreased the difference in resources for episodes that coded the variable versus those that did not and, therefore, may have caused the variable to become insignificant or to have minimal impact on resource costs, leading to its elimination from the model.

When evaluating the points associated with each leg of the model, it is important to examine the thresholds for each leg. For example, the clinical thresholds described in the proposed rule have fewer points associated with them for the 0 to 13 therapy visit episodes. Therefore, while there may be fewer points associated with some of the variables within the 0 to 13 therapy visit legs, there is also a lower threshold for the clinical levels. In order to determine the thresholds, we put episodes into five groups (early episodes, 0 to 13 therapy visits, early episodes, 14–19 therapy visits, late episodes, 0 to 13 therapy visits, late episodes, 14–19 therapy visits, and 20+ therapy visit episodes) for both the clinical and the functional dimensions. We then attempt to divide the episodes within each group into thirds in order to set the thresholds. Therefore, regardless of the points, on average, the most resource-intensive episodes will be placed in the highest clinical or functional level. It is also

worth noting that, with the CY 2015 recalibration, additional variables received points in the estimation of the 4-equation model that did not receive points in the CY 2012 recalibration. Again, the outcomes of the models are guided by the data and reflect recent (2013) utilization patterns. This approach increases payments for the HHRGs where resources are being provided where they were not previously and decreases payment for the HHRGs where resources are not being provided where they were previously. The intent is to create payments that more accurately reflect the costs that agencies incur.

Comment: A commenter also stated that this is the third year in a row that the HH PPS has had different case-mix weights and that this may be an indicator of uncertainty by CMS. Another commenter stated that the recalibration of the weights is being recommended after having just recently been changed the prior year and that there is no consistency in the change.

Response: We would like to clarify that fundamentally we have not changed the weights since CY 2012. We previously recalibrated the case-mix weights in 2012 and did not change the weights in CY 2013. For CY 2014, while we lowered the case-mix weights to an average case-mix weight of 1.0000, we did not adjust the weights relative to one another. We instead decreased each case-mix weight by the same factor (1.3464). In the CY 2015 proposed rule, we proposed to recalibrate the case-mix weights with more current data, adjusting the weights relative to one another. To the greatest extent possible, we are attempting to use recent data to calibrate the payment models to ensure payments accurately reflect current resource use in home health episodes.

Comment: A commenter found the data CMS is basing its proposals on to be puzzling and mentioned that the payment system does not allow for reporting of time devoted to patient care that is not visit time. The commenter stated that dementia and brain disorders involve significant time outside of the visit.

Response: Section 1861(m) of the Act defines home health services as ''items and services furnished to an individual [. . .] provided on a visiting basis *in a place of residence used as such individual's home . . .*'' (emphasis added). Under certain circumstances, services may be provided via a telecommunications system, but these services do not substitute for in-person home health services and are not considered a home health visit for purposes of home health eligibility or payment (see section 1895(e)(1) of the Act). In addition, the commenter provided no supporting data explaining why home health services for patients suffering from dementia and brain disorders would require reimbursement exceeding the typical case management/care coordination functions that are inherent in managing patients in the home. We also note that while the case-mix recalibration does not include time outside of the visit, the base rate should capture other expenses related to patient care, such as travel costs, etc. An assumption since the original development of the HH PPS, supported by internal studies of cost report data, has been that visit time is approximately proportional to the total cost of caring for a patient during an episode.

Comment: Commenters expressed concerns with the effects the recalibrated weights will have when coupled with the rebasing reductions. A commenter stated that the combination of the recalibrated case-mix weights and the change in base rate brings about the equivalent of about a three point reduction in payments. A commenter stated that it makes sense to update case-mix points when statistical analyses warrant it but that it seems that most adjustments in recent years were done to reduce payments to home health agencies. A commenter stated that the changes in the case-mix points and thresholds for scoring the episode constitute a further reduction in payment beyond the required reduction and recalibration of the case-mix weights for CY 2015.

Response: The CY 2015 case-mix recalibration is done in a budget neutral manner. While we recalibrated the CY 2015 case-mix weights to an average case-mix weight of 1.00, we also proposed an increase to the base rate of 2.37 percent in order to ensure that there are no changes in aggregate payments due to the recalibration. The weights are only changing relative to one another and do not result in an overall reduction in HH PPS payments due to the recalibration of the case-mix weights.

Comment: A commenter stated that case-mix weights are continuing to be recalibrated to 1.000 but that many payments to home health do not result in the episodic payment including Partial Episode Payments, payments for low utilization payment adjustment episodes, outliers, and others.

Response: We believe the commenter is implying that the case-mix recalibration is not budget neutral given that LUPA, outlier episodes, etc. are not included in the case-mix weight recalibration. We note the LUPA episodes are paid on a per-visit basis and are not paid using the case-mix weights. Therefore, they were not included when performing the recalibration. We note that all episodes, including partial episode payment episodes and outlier episodes, are included when calculating the budget neutrality factor in order to ensure that total payments would be the same when comparing the CY 2015 weights to the CY 2014 weights. However, outliers are not included in the data when doing the case-mix recalibration because outlier episodes contain utilization patterns that are atypical. The outliers' utilization presumably reflects unusually high patient need for services that is not easily predictable in statistical data. In addition, due to the concentration of outlier episodes in suspect billing areas, we question some of the utilization data for outlier episodes. We would also like to note that outlier episodes receive additional payment when the imputed cost exceeds a certain threshold and therefore, receive additional payment outside of the case-mix system.

Comment: A commenter stated that the R-squared value of the payment regression model has increased from the 2012 payment regression model even though variables were dropped from the four-equation model. The commenter stated that less variables in the four-equation model should weaken the R-squared value.

Response: We do note that while the R-squared value for the payment regression increased for the CY 2015 payment regression model when compared to the CY 2012 payment regression model, the R-squared value for the CY 2015 four-equation model did decrease when compared to the R-squared value for the CY 2012 four-equation model, from 0.462 to 0.427. However, we point out that for the CY 2015 four-equation model and payment regression model, we used 2013 data. For the CY 2012 four-equation model, we used 2005 data and for the CY 2012 payment regression model, we used data from 2007. R-squared values will change depending on what data are used and cannot be directly compared.

Comment: Commenters supported the idea of recalibrating the weights with newer data but expressed concerns with the resulting proposed weights. Commenters stated their concerns with the continued use of therapy thresholds in the case-mix system. Commenters recommended that the therapy thresholds be eliminated from the payment system and that home health services be paid solely based on patient characteristics. A commenter stated that

though CMS has made efforts to reduce payments for therapy episodes, the incentives of the therapy thresholds, with more visits receiving higher payments, still remain in effect. The commenter stated that the adjustments to the case-mix weights would not be necessary if the therapy thresholds were eliminated.

Response: We recognize the issues around the use of the therapy thresholds and the use of therapy utilization in the payment system. We are currently looking into findings of the home health study authorized by section 3131(d) of the Affordable Care Act and payment reform options, including alternate ways to explain the amount of therapy resources without using therapy utilization variables. Further research is needed to find alternatives that will compensate for some of the loss of the explanatory power associated with the removal of the therapy utilization variables.

Comment: Several commenters were concerned about the implications for agencies of adjusting to several successive recalibrations. Commenters said recalibrations cause instability for HHAs, with one saying recalibrations were inconsistent with one another. A commenter was concerned that multiple recalibrations make calculations with the case mix weights useless as a comparative tool over time. This commenter also cited problems with calculations from including therapy utilization and by the constant annual revision to the various OASIS items or diagnoses included/excluded.

Response: We note that other post-acute payment systems, such as the inpatient rehabilitation facility PPS and acute inpatient PPS, recalibrate their case-mix weights annually. The differences in the recalibration results for the CY 2012 recalibration and the CY 2015 recalibration largely result from the six to eight year difference in the data used. We expect future annual recalibrations to have less significant changes in the case-mix points and values. With regard to the use of therapy utilization in our methodology, as stated in our response above, we are looking into alternate ways to explain the amount of therapy resources. Since the 2008 refinements, there have been no changes to the payment items on the OASIS. In addition, besides last year's changes to the ICD–9–CM codes included into the case-mix system (effective January 1, 2014 and therefore not reflected in the CY 2013 data used to recalibration the CY 2015 case-mix weights) and the removal of the hypertension codes in 2012, we did not make significant changes to the diagnoses included or excluded in the case-mix system. We also note in 2013, changes in the rules for using the payment diagnosis field were simulated and the simulations showed impacts in payment of less than one percent.

Comment: A commenter stated that to the extent that CMS is pursuing the adjustments to the weights for 2015, the agency should analyze the payment-to-cost ratios for the proposed payment weights before and after the manual adjustment, similar to the analysis conducted during the CY 2012 recalibration. The commenter stated that this additional analysis would allow CMS to assess whether these adjustments equalize the financial incentives for therapy and non-therapy episodes. Another commenter urged CMS to adjust the CY 2015 case-mix weights to ensure appropriate use of therapy visits and move reimbursement for therapy-based episodes towards actual costs incurred. Commenters recommended that CMS conduct a thorough validation review of the proposed case-mix weight recalibration and evaluate the potential impact on utilization, spending, access to care, and other relevant matters. Other commenters urged CMS to re-examine the case-mix recalibration and refine it to control for variables that might skew outcomes and ensure that the end result does not create rewards for high therapy resource use that may be inappropriate. A commenter suggested that CMS revisit the case-mix weight recalibration to accomplish its stated intention or alternatively provide a detailed explanation how the recalibrated case-mix weights are consistent with its intent. The commenter also stated that there has been no testing to determine whether the adjustments will achieve the desired outcomes. The commenter recommended that CMS retain the current case-mix weights until an approach to recalibration that actually achieves the desired outcomes can be developed and tested. The commenter stated that the changes to the payment system don't seem to have achieved the desired impact.

Response: We performed an analysis of the payment-to-cost ratio for episodes with varying levels of therapy visits. This analysis used cost report data to estimate episode cost and showed that the payment to cost ratios across the varying levels of therapy visits for the recalibrated weights were similar to the payment to cost ratios for the current weights. The analysis also justified the need for the continued adjustments (finalized in CY 2012) to be applied to the raw weights to lower the case-mix weights for high therapy episodes. The payment-to-cost ratios across the individual therapy visits were all relatively similar to each other, with some exceptions in the tails of the distribution, and indicated that there may not be a strong incentive to provide unnecessary amounts of therapy visits. The goal of the recalibration is to better align payment with current costs and we believe the recalibration achieves this.

Comment: Commenters expressed their support for CMS' decision to apply a full case-mix budget neutrality factor rather than a reduced case-mix budget neutrality factor which would take into account nominal case-mix growth. However, they expressed concern about the uncertainty for providers in planning for projected rates in CY 2015 and beyond given the possibility of case-mix reductions in the future. Commenters urged CMS to closely collaborate with the industry and stakeholders to ensure that the appropriate analysis is conducted in evaluating case-mix growth before proposing case-mix reductions in the future. Another commenter suggested that CMS perform a comprehensive study of individual patient clinical records before asserting that case-mix growth has occurred by anything other than necessary clinical care being provided. Another commenter urged CMS to use their enforcement authority to conduct targeted claims reviews and deny payment for claims where the case-mix weight is not supported by the plan of care rather than cut the national standardized episode rate for all agencies. Yet another commenter stated that case-mix change should not be measured using 1999 data as a baseline and that HHAs are providing better care for a more needy clinical population. Other commenters questioned the methodology used to determine real and nominal case-mix.

Response: While we appreciate the commenters' suggestion about the clinical record review, we note that our resources are not sufficient to conduct a review of patient records and/or claims on a scale that would be required to counteract the broad-based uptrend in case-mix weights; therefore, we cannot perform the review as suggested. However, we note that the MACs, in conjunction with supplemental review contractors, perform medical review of claims. When they perform medical review, they review the plan of care and OASIS and make adjustments to HHRGs if they deem that the documentation is not sufficient to support what was billed by the agency. Furthermore, we note that our statistical methods using available administrative data are

feasible and sufficiently reliable to utilize for the purpose of case-mix reductions.

With regard to the comments about patient severity, as stated in the CY 2012 proposed rule, a detailed analysis of Medicare Expenditure Panel Survey (MEPS) data (which is independent of our real case-mix model) was performed to examine the severity of the Medicare home health population. The trends in health status from 2000 to 2008 were analyzed. The analysis showed a slight increase in the overall health status of the Medicare home health population, and in particular, the percent of home health Medicare beneficiaries experiencing ''extreme'' or ''quite a bit'' of work-limiting pain decreased substantially, from 56.6 percent in 2000 to 45.4 percent in 2008 ($p = 0.039$). While we recognize that there are some limitations to this analysis, we conclude that the results of this analysis provide no evidence of an increase in patient severity from 2000 to 2008.

In addition, we would like to note that during the CY 2012 rulemaking, we incorporated HCC data, which is used by CMS to risk-adjust payments to managed care organization in the Medicare program, in our model to assess real case-mix growth. Our findings of real and nominal case-mix growth, even when incorporating HCC data, were consistent with past results. Most of the case-mix change was identified as nominal case-mix change. We will continue to solicit suggestions for other data that can be incorporated into our analysis of real and nominal growth and solicit suggestions on possible ways to improve our models. We plan to continue to monitor real and nominal case-mix growth and may propose additional case-mix reductions as necessary.

Comment: One commenter stated that CMS has adjusted payments in 2008 to 2013 based on an analysis of changes in coding not related to changes in patient severity, but that CMS has not proposed a coding adjustment for 2015. The commenter stated that given the history of coding increases not attributable to severity, CMS should analyze the nominal case-mix change in the reported average case-mix for more recent years and implement additional payment reductions as warranted.

Response: We agree and we will continue to monitor nominal case-mix growth and propose case-mix adjustments, as necessary. We also note that annually recalibrating (and normalizing the weights to 1.00) may minimize nominal case-mix growth in future years.

Comment: Another commenter stated that CMS should address and eliminate fraudulent activities in a targeted manner that does not burden the whole industry for the actions of a small number of bad actors. The commenter stated that CMS should target bad actors rather than continue to implement across the board reductions that could reduce the number and quality of home health providers.

Response: For a variety of reasons, as we have noted in previous regulations, we have not proposed targeted reductions for nominal case-mix change. Many agencies have small patient populations, which would make it practically impossible to reliably measure nominal case-mix change at the agency level. Further, we believe changes and improvements in coding practices have been widespread, making it difficult to clearly categorize agencies into high and low coding-change groups. As discussed in the CY 2012 final rule, when performing an independent review of our case-mix measurement methodology, Dr. David Grabowski and his team at Harvard University agreed with our reasons for not proposing targeted reductions, stating their concerns about the small sample size of many agencies and their findings of significant nominal case-mix increases across different classes of agencies.

We note that although we have stated in past regulations that a targeted system would be administratively burdensome, the reasons we have just presented go beyond administrative complexity. We do not agree that agency-specific case-mix levels can precisely differentiate agencies with inappropriate coding practices from other agencies that are coding appropriately. System wide, case-mix levels have risen over time while data on patient characteristics indicate little change in patient severity over time. That is, the main problem is not the level of case-mix reached over a period of time, but the amount of change in the billed case-mix not attributable to underlying changes in actual patient severity. We will continue to monitor nominal case-mix growth and determine whether case-mix reductions are needed.

Comment: Commenters questioned why CMS has not expanded the recalibration analysis to include additional variables that impact the cost of home health services to Medicare beneficiaries, such as those examined in the home health study and associated with low-income beneficiaries, beneficiaries in medically underserved areas, and those with varying levels of severity of illness. Commenters urged CMS to incorporate findings from the access study into the case-mix system for CY 2015. A commenter expressed disappointment that CMS continued to rely on the current case-mix system rather than testing and implementing new models. The commenter stated that the current case-mix system and proposed adjustments have reached a level of complexity that make it challenging to determine the accuracy of the proposed technical refinements. The commenter stated that the inaccuracies in the current system, resulting from the limitations of the current OASIS variables and the use of average costs that do not represent the full costs of treating more complex patients, continue to result in underpayment for patients whose resource use and cost of care are not fully captured in the case-mix weights. Another commenter suggested that CMS work with the industry to develop the case-mix methodology.

Response: We are currently doing follow-on work to the home health study to explore findings and recommendations from the home health study on access to care for vulnerable populations. Under this contract, we are also exploring payment reform options to better capture costs associated with the various types of home health patients. However, the project is in its preliminary stages and will take some time to complete. We plan to provide updates on the follow on study and payment reform work in future rulemaking and plan to consult with stakeholders once further progress has been made.

Comment: While outside the scope of the rule, some commenters provided suggestions for our payment reform work.

Response: We thank the commenter for their input. We will take their comments into consideration for our payment reform work.

Final Decision: We are finalizing the points for the case-mix variables, the revised thresholds for the clinical and functional levels, and the case-mix weights for CY 2015 shown in the tables above. We are also finalizing our proposal to recalibrate the case-mix weights every year with more current data. We will continue to monitor case-mix growth and may consider whether to propose nominal case-mix reductions in future rulemaking.

D. CY 2015 Home Health Rate Update

1. CY 2015 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2015 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 percentage increase for CY 2015 is based on IHS Global Insight Inc.'s (IGI) third quarter 2014 forecast with historical data through the second quarter of 2014. The home health market basket percentage increase for CY 2015 is 2.6 percent. The HH market basket was rebased and revised in CY 2013. A detailed description of how we derive the HH market basket is available in the CY 2013 HH PPS final rule (77 FR 67080, 67090).

For CY 2015, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket percentage under the HH prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. The statute defines the productivity adjustment, described in section 1886(d)(3)(B)(xi)(II) of the Act, to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period)(the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data. We note that the proposed methodology for calculating and applying the MFP adjustment to the HHA payment update is similar to the methodology used in other Medicare provider payment systems as required by section 3401 of the Affordable Care Act. Please refer to the CY 2015 HH PPS proposed rule (79 FR 38384 through 38386) for more detailed information regarding the computation of the MFP adjustment.

We did not receive any comments on our proposal related to the computation of the statutorily-required productivity adjustment. Therefore, we are finalizing our proposal to adjust the HH market basket percentage increase by the MFP adjustment as discussed in the proposed rule. The CY 2015 HH market basket percentage of 2.6 percent will be reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2015) of 0.5 percent, which is based on IGI's third quarter 2014 forecast. The resulting MFP-adjusted HH market basket update is equal to 2.1 percent, or 2.6 percent less 0.5 percentage point.

Section 1895(b)(3)(B) of the Act requires that the home health market basket percentage increase 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 2015, the home health market basket update will be 0.1 percent (2.1 percent minus 2.0 percentage points).

2. Home Health Care Quality Reporting Program (HH QRP)

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

The successful development of the Home Health Quality Reporting Program (HH QRP) that promotes the delivery of high quality healthcare services is one of our paramount concerns in administering the home health program. We seek to adopt measures for the HH QRP that promote more efficient and safer care. Our measure selection activities for the HH QRP take into consideration input we receive from the Measure Applications Partnership (MAP), convened by the National Quality Forum (NQF) as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS.

More details about the pre-rulemaking process can be found at *http://www.qualityforum.org/map.*

MAP reports to view and download are available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.*

Our measure development and selection activities for the HH QRP take into account national priorities, such as those established by the National Priorities Partnership (*http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx*), the Department of Health & Human Services (HHS) Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html,* the National Quality Strategy (NQS) (*http://www.ahrq.gov/workingforquality/reports.htm*), and the CMS Quality Strategy (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*). To the extent practicable, we have sought to adopt measures that have been endorsed by the national consensus organization under contract to endorse standardized healthcare quality measures under section 1890 of the Act, recommended by multi-stakeholder organizations, and developed with the input of patients, providers, purchasers/payers, and other stakeholders. At this time, the NQF is the national consensus organization that is under contract with HHS to provide review and endorsement of quality measures.

b. Background and Quality Reporting Requirements

Section 1895(b)(3)(B)(v)(II) of the Act states that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.''

In addition, section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.'' This requirement has been codified in regulations at § 484.225(i). HHAs that meet the quality data reporting requirements are eligible for the full home health (HH) market basket percentage increase. HHAs that do not meet the reporting requirements are subject to a 2 percentage point reduction to the HH market basket increase.

Section 1895(b)(3)(B)(v)(III) of the Act further states that ''[t]he Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.''

Medicare home health regulations, as codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of

Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. We provide quality measure data to HHAs via the Certification and Survey Provider Enhanced Reports (CASPER reports) which are available on the CMS Health Care Quality Improvement System (QIES). A subset of the HH quality measures has been publicly reported on the Home Health Compare (HH Compare) Web site since 2003. The CY 2012 HH PPS final rule (76 FR 68576), identifies the current HH QRP measures. The selected measures that are made available to the public can be viewed on the HH Compare Web site located at *http://www.medicare.gov/HHCompare/Home.asp.* As stated in the CY 2012 and CY 2013 HH PPS final rules (76 FR 68575 and 77 FR 67093, respectively), we finalized that we will also use measures derived from Medicare claims data to measure HH quality.

In the CY 2014 HH PPS final rule, we finalized a proposal to add two claims-based measures to the HH QRP, and also stated that we would begin reporting the data from these measures to HHAs beginning in CY 2014. These claims based measures are: (1) Rehospitalization during the first 30 days of HH; and (2) Emergency Department Use without Hospital Readmission during the first 30 days of HH. Also in this rule, we finalized our proposal to reduce the number of process measures reported on the CASPER reports by eliminating the stratification by episode length for 9 process measures. While no timeframe was given for the removal of these measures, we have scheduled their removal from the CASPER folders in October 2014. In addition, five short stay measures which had previously been reported on HH Compare were recently removed from public reporting and replaced with non-stratified ''all episodes of care'' versions of these measures.

Comment: One commenter urged CMS to only adopt quality measures that have been endorsed by the Measure Applications Partnership (MAP) and National Quality Forum (NQF).

Response: To the extent practicable, we seek to adopt measures that have been endorsed by a consensus based entity, such as NQF. We also intend to continue seeking input from the MAP as part of the pre-rulemaking process.

Comment: One commenter asked CMS to comment on the timeframe for the public release of the two ''post-acute 30 day measures.''

Response: We believe the commenter is requesting information about the status of public reporting for the two HH claims based measures titled ''Rehospitalization during the First 30 Days of HH'' and ''Emergency Department Use without Readmission during the First 30 Days of HH'' that were finalized in the CY 2014 HH PPS final rule (78 FR 72256). In the CY 2014 HH PPS final rule, we stated that ''these measures will be added to HH Compare for public reporting in CY 2015'' (78 FR 72298.).

c. OASIS Data Submission and OASIS Data for Annual Payment Update

(1) Regulatory Authority

The HH conditions of participation (CoPs) at § 484.55(d) require that the comprehensive assessment must be updated and revised (including the administration of the OASIS) no less frequently than: (1) The last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode; (2) within 48 hours of the patient's return to the home from a hospital admission of 24-hours or more for any reason other than diagnostic tests; and (3) at discharge.

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

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

- Receiving only non-skilled services;
- For whom neither Medicare nor Medicaid is paying for HH care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Receiving pre- or post-partum services; or
- Under the age of 18 years.

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), HHAs that become Medicare-certified on or after May 31 of the preceding year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following year. For example, HHAs certified on or after May 31, 2013 are not subject to the 2 percentage point reduction to their market basket update for CY 2014. These exclusions only affect quality reporting requirements and do not affect the HHAs' reporting responsibilities as announced in the December 23, 2005 final rule, ''Medicare and Medicaid Programs; Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies'' (70 FR 76202).

(2) HH QRP Requirements for CY 2015 Payment and Subsequent Years

In the CY 2014 HH PPS Final rule (78 FR 72297), we finalized a proposal to consider OASIS assessments submitted by HHAs to CMS in compliance with HH CoPs and Conditions for Payment for episodes beginning on or after July 1, 2012, and before July 1, 2013 as fulfilling one portion of the quality reporting requirement for CY 2014. In addition, we finalized a proposal to continue this pattern for each subsequent year beyond CY 2014. OASIS assessments submitted for episodes beginning on July 1st of the calendar year 2 years prior to the calendar year of the Annual Payment Update (APU) effective date and ending June 30th of the calendar year 1 year prior to the calendar year of the APU effective date fulfill the OASIS portion of the HH QRP requirement.

(3) Establishing a ''Pay-for-Reporting'' Performance Requirement for Submission of OASIS Quality Data

Section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.'' This ''pay-for-reporting'' requirement was implemented on January 1, 2007. However, to date, the quantity of OASIS assessments each HHA must submit to meet this requirement has never been proposed and finalized through rulemaking or through the sub-regulatory process. We believe that this matter should be addressed for several reasons.

We believe that defining a more explicit performance requirement for

the submission of OASIS data by HHAs would better meet section 5201(c)(2) of the Deficit Reduction Act of 2005 (DRA), which requires that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.''

In February 2012, the Department of Health & Human Services Office of the Inspector General (OIG) performed a study to: (1) Determine the extent to which HHAs met federal reporting requirements for the OASIS data; (2) to determine the extent to which states met federal reporting requirements for OASIS data; and (3) to determine the extent to which the CMS was overseeing the accuracy and completeness of OASIS data submitted by HHAs. In a report entitled, ''Limited Oversight of Home Health Agency OASIS Data,''[24] the OIG stated their finding that ''CMS did not ensure the accuracy or completeness of OASIS data.'' The OIG recommended that we ''identify all HHAs that failed to submit OASIS data and apply the 2 percent payment reduction to them''. We believe that establishing a performance requirement for submission of OASIS quality data would be responsive to the recommendations of the OIG.

In response to these requirements and the OIG report, we designed a pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data. The performance system is based on the principle that each HHA is expected to submit a minimum set of two ''matching'' assessments for each patient admitted to their agency. These matching assessments together create what is considered a ''quality episode of care'', consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment. However, it was determined that there are several scenarios that could meet this ''matching assessment requirement'' of the new pay-for-reporting performance requirement. These scenarios or ''quality assessments,'' are defined as assessments that create a quality episode of care during the reporting period or could create a quality episode if the reporting period were expanded to an earlier reporting period or into the next reporting period.

Seven types of assessments submitted by an HHA fit this definition of a quality assessment. These are:

- A Start of Care (SOC) or Resumption of Care (ROC) assessment that has a matching End of Care (EOC) assessment. EOC assessments are assessments that are conducted at transfer to an inpatient facility (with or without discharge), death, or discharge from HH care. These two assessments (the SOC or ROC assessment and the EOC assessment) create a regular quality episode of care and both count as quality assessments.
- A SOC/ROC assessment that could begin an episode of care, but occurs in the last 60 days of the performance period. This is labeled as a ''Late SOC/ROC'' quality assessment.
- An EOC assessment that could end an episode of care that began in the previous reporting period, (that is, an EOC that occurs in the first 60 days of the performance period.) This is labeled as an ''Early EOC'' quality assessment.
- A SOC/ROC assessment that is followed by one or more follow-up assessments, the last of which occurs in the last 60 days of the performance period. This is labeled as an ''SOC/ROC Pseudo Episode'' quality assessment.
- An EOC assessment is preceded by one or more follow-up assessments, the last of which occurs in the first 60 days of the performance period. This is labeled an ''EOC Pseudo Episode'' quality assessment.
- A SOC/ROC assessment that is part of a known one-visit episode. This is labeled as a ''One-Visit episode'' quality assessment.
- SOC, ROC, and EOC assessments that do not meet any of these definitions are labeled as ''Non-Quality'' assessments.
- Follow-up assessments (that is, where the M0100 Reason for Assessment = '04' or '05') are considered ''Neutral'' assessments and do not count toward or against the pay for reporting performance requirement.

Compliance with this performance requirement can be measured through the use of an uncomplicated mathematical formula. This pay for reporting performance requirement metric has been titled as the ''Quality Assessments Only'' (QAO) formula because only those OASIS assessments that contribute, or could contribute, to creating a quality episode of care are included in the computation. The formula based on this definition is as follows:

$$QAO = \frac{(\#\ of\ Quality\ Assessments)}{(\#\ of\ Quality\ Assessments\ +\ \#\ of\ NonQuality\ Assessments)} * 100$$

Our ultimate goal is to require all HHAs to achieve a pay-for-reporting performance requirement compliance rate of 90 percent or more, as calculated using the QAO metric illustrated above. However, we proposed to implement this performance requirement in an incremental fashion over a 3 year period. We proposed to require each HHA to reach a compliance rate of 70 percent or better during the first reporting period [25] that the new pay-for-reporting performance requirement is implemented. We further proposed to increase the pay-for-reporting performance requirement by 10 percent in the second reporting period, and then by an additional 10 percent in the third reporting period until a pay-for-reporting performance level of 90 percent is reached.

To summarize, we proposed to implement the pay-for-reporting performance requirement beginning with all episodes of care that occur on or after July 1, 2015, in accordance with the following schedule:

- For episodes beginning on or after July 1st, 2015 and before June 30th, 2016, HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2017.
- For episodes beginning on or after July 1st, 2016 and before June 30th, 2017, HHAs must score at least 80 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2018.

[24] *http://oig.hhs.gov/oei/reports/oei-01-10-00460.asp*

[25] The term ''reporting period'' is defined as the submission of OASIS assessments for episodes between July 1 (of the calendar year two years prior to the calendar year of the APU effective date) through the following June 30th (of the calendar year one year prior to the calendar year of the APU effective date) each year.

• For episodes beginning on or after July 1st, 2017, and thereafter, and before June 30th, 2018 and thereafter, HHAs must score at least 90 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2019, and each subsequent year thereafter.

We solicited public comment on our proposal to implement the pay-for-reporting performance requirement, as described previously, for the HH QRP. We received the following comments in response to our proposal:

Comment: MedPAC submitted a comment in which they expressed full support for the proposal to establish a minimum requirement for submission of OASIS assessments. MedPAC stated that ''the requirement for submission of OASIS data to receive a full payment update has been in effect for many years, and agencies should have many years of experience with the transmission of this data'' and suggested that CMS consider phasing in the requirement at a faster rate, given the familiarity of HHAs with these processes. MedPAC recommended raising the threshold to 90 percent in the second year. Another commenter, who stated support for this proposal, suggested increasing the compliance thresholds to 75 percent, 85 percent and 95 percent (instead of the 70 percent, 80 percent and 90 percent threshold that were proposed). Another commenter suggested that CMS should carefully monitor compliance rates over the next two years to determine if a 90 percent compliance rate is a realistic goal.

Several commenters supported our proposal to establish a minimum requirement for submission of OASIS assessments for a variety of reasons. One commenter stated a belief that this proposal demonstrates CMS' efforts to obtain more complete patient data sets. Another commenter expressed an opinion that the proposed OASIS minimum reporting requirement is a program integrity reform and cost cutting measure that is preferable to the across the board payment cuts established by CMS in previous HH PPS rules.

Response: We thank MedPAC and other commenters who support our proposal to establish a pay-for-reporting performance requirement for the HH QRP. We agree that the requirements for OASIS reporting have been in effect for many years. The HH CoPs which are codified at 42 CFR 484.55 and mandate use of the OASIS data set when evaluating adult non-maternity patients receiving skilled services were established in 1999 (64 FR 3764 through 3784). OASIS reporting was first implemented on July 19, 1999 and in 2007, OASIS reporting became mandatory for quality reporting purposes under section 1895(b)(3)(B)(v)(I) of the Act. HHAs have been required to submit OASIS data as a condition of payment of their Medicare claims since 2010. As HHAs have been required to report OASIS data for the past 15 years as a CoP in the Medicare program and as a condition of payment of their Medicare claims for the past 4 years, our establishment of a minimum threshold for OASIS reporting should not place any new or additional burden on HHAs.

Our ultimate goal is to require all HHAs to achieve a pay-for-reporting performance requirement compliance rate of 90 percent or more, as calculated using the QAO metric described and in this section. In the proposed rule, we proposed to require each HHA to reach a compliance rate of 70 percent or better during the first reporting period that the new pay-for-reporting performance requirement is implemented. We believe that use of the 70 percent standard is one that is attainable by any HHA, whether it is a large corporate entity or very small family run business. We had further proposed to increase the performance requirement by 10 percent in the second reporting period, and then by an additional 10 percent in the third reporting period until a pay-for-reporting performance requirement of 90 percent is reached, because we believed that this schedule would promote successful performance by all HHAs.

However, after carefully considering the comments submitted, we have reconsidered our proposal for implementation of a ''pay-for-performance'' performance requirement over a 3 year period. MedPAC suggested that CMS consider phasing in the OASIS reporting requirement at a faster rate, given the familiarity that HHAs have with the OASIS process. MedPAC recommended raising the threshold to 90 percent in the second year.

We agree with MedPAC's contention that HHAs have been statutorily required to report OASIS for a number of years and therefore should have many years of experience with the collection of OASIS data and transmission of this data to CMS. Given the length of time that HHAs have been mandated to report OASIS data, we believe that HHAs will adapt quickly to the implementation of the ''pay-for-reporting'' performance requirement, if phased in over a 2 year period. On the other hand, the ''pay-for-reporting'' performance requirement is a new reporting requirement that can have a significant financial impact any HHA that is not able to meet the requirements.

We believe that it is best to proceed with the establishment of the 70 percent reporting requirement during the first reporting period (that is, July 1, 2015 through June 30, 2016) and will finalize this part of our proposal. However, we will not finalize our proposal to increase the reporting requirement in 10 percent increments over a 2 year period until the maximum rate of 90 percent is reached. In consideration of the recommendations made, we plan to monitor provider performance under the ''pay-for-reporting'' performance requirement during the time period of July 1, 2014 through June 30, 2015. We will then use such information, as available, to make a determination about what the ''pay-for-reporting'' performance requirement will be set at in the 2nd and subsequent years. For example, we will review OASIS data from a recent reporting period simulating the ''pay-for reporting'' performance 70 percent submission requirement to determine the ''hypothetical performance'' of each HHA ''as if'' the ''pay for reporting'' performance requirement were in effect during the reporting period preceding its implementation. We will provide a report to each HHA of their ''hypothetical performance'' under the ''pay for reporting'' performance requirement during the 2014–2015 ''pre-implementation reporting period.'' We will also consider provider performance during the first part of the first year of the ''pay for reporting'' performance requirement as data are available in determining the OASIS reporting requirement for the 2nd and subsequent years.

Comment: A commenter expressed agreement with our proposal to implement the OASIS minimum reporting requirements over a 3 year period, but strongly recommended that such requirements be limited to the OASIS data sets collected for Medicare PPS episodes only. This commenter stated a belief that it would be too burdensome if HHAs were required to complete OASIS assessments for patients on other payment programs.

Response: Patients receiving care under a Medicare or Medicaid managed care plan are not excluded from the OASIS reporting requirements, and HHAs are required to submit OASIS assessments for these patients. OASIS reporting is mandated for all Medicare beneficiaries (under 42 CFR 484.250(a), 484.225(i), and 484.55). The HH CoPs require that the Home Health Registered

Nurse (HH RN) or qualified therapist perform an initial assessment within 48 hours of referral, within 48 hours of the patient's return home, or on the physician-ordered start of care date. The HH RN or qualified therapist must also complete a comprehensive assessment within 5 days from the start of care. During these assessments, the HH RN or qualified therapist must determine the patient's eligibility for the Medicare HH benefit, including homebound status (42 CFR 484.55(a)(1) and 42 CFR 484.55 (b)). In addition, the requirement for OASIS reporting on Medicare and Medicaid Managed Care patients was established in a final rule titled ''Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies Final Rule'' dated December 23, 2005 (70 FR 76202), which stated the following:

In the January 25, 1999, interim final rule with comment period (64 FR 3749), we generally mandated that all HHAs participating in Medicare and Medicaid (including managed care organizations providing home health services to Medicare and Medicaid beneficiaries) report their OASIS data to the database we established within each State via electronic transmission. (76 FR 76200).

We do not believe that there is more burden associated with the collection of OASIS assessment data for a Medicare Managed Care patient than there is for a HH patient that receives traditional Medicare PPS benefits. The requirements for the HH RN or qualified therapist to perform an initial and comprehensive assessment and complete all required OASIS assessments is the same for all Medicare patients regardless of the type of Medicare benefits they receive. The completion of these activities is a condition of payment of both Medicare PPS and managed care claims.

Comment: A commenter, while in general agreement with the establishment of a minimum reporting requirement for OASIS reporting, expressed disagreement with implementation of this requirement on July 1, 2015. This commenter voiced the opinion that HHAs should first be informed of their current OASIS submission compliance rate, so they have an opportunity to improve, if below the 70 percent threshold. Another commenter suggested that CMS provide each HHA with their current OASIS reporting compliance rates to allow them to assess and understand their compliance levels and create a benchmark against which they can seek to improve over time. Another commenter requested that CMS publish the current rate of HHA compliance with OASIS reporting and recommended that the new compliance standard be based on incremental increases from those rates.

Response: HHAs have been required to report OASIS data on 100 percent of their Medicare beneficiary patients for the past 15 years as a CoP and as a condition of payment of their Medicare claims. Also, since 2007, HHAs have been required to report OASIS quality data on 100 percent of their Medicare beneficiary patients in order to receive their full yearly market basket update.

We do not agree that revealing sub-par provider compliance rates will be helpful to providers as several commenters have requested. Our establishment of the pay-for reporting performance requirement is a means by which we can measure HHA compliance with the established and long standing OASIS reporting requirements, while allowing HHAs a 2 year period to bring their performance up to the 90 percent compliance level. As the OASIS reporting requirements have been in existence for 15 years, HHAs should already possess knowledge of these requirements and know what they need to do to bring their agency into compliance. Furthermore, as OASIS reporting on each Medicare beneficiary is a requirement for payment of Medicare billing claims and also a HH CoP, our establishment of a minimum threshold for OASIS reporting should not place any new or additional burden on HHAs.

Comment: Several commenters, while in general agreement with this proposal, requested that CMS provide clarification of the term ''submission'' and inquired whether this requires both submission and acceptance of OASIS data by the state agency. Another commenter sought assurance that HHAs will not be penalized for delayed acceptance of OASIS data by state agency due to CMS server/IT issues.

Response: The pay-for reporting performance requirements will go into effect on July 1, 2015. However, on January 1, 2015, the data submission process for OASIS will convert from the current state-based OASIS submission system to a new national OASIS submission system known as the Assessment Submission and Processing (ASAP) System.[26] Therefore, the commenter's question about whether successful submission requires both submission and acceptance of OASIS data by the state agency is moot because the state-based OASIS submission system will not be in existence.

On July 1, 2015, when the pay-for reporting performance requirement of 70 percent goes into effect, providers will be required to submit their OASIS assessment data into the ASAP system. Successful submission of an OASIS assessment will consist of the submission of the data into the ASAP system with a receipt of no fatal error messages. Error messages received during submission can be an indication of a problem that occurred during the submission process and could also be an indication that the OASIS assessment was rejected. Successful submission can be verified by ascertaining that the submitted assessment data resides in the national database after the assessment has met all of the quality standards for completeness and accuracy during the submission process.

Should one or more OASIS assessments submitted by a HHA be rejected due to an IT/servers issue cause by CMS, we may, at our discretion, excuse the non-submission of OASIS data. We anticipate that such a scenario would rarely, if ever, occur. In the event that a HHA believes they were unable to submit OASIS assessments due to an IT/server issue on the part of CMS, the HHA should be prepared to provide any documentation or proof available which demonstrates that no fault on their part contributed to the failure of the OASIS records to transmit to CMS.

Comment: Several commenters suggested that CMS provide comprehensive education on the new OASIS minimum reporting requirements for at least 6 months before it is effective. One commenter stated a belief that provider education is especially necessary since the failure to meet the submission threshold would result in a 2 percent reduction in payment for an entire calendar year.

Response: We agree that educating HH providers about the new OASIS data submission requirements is very important and necessary. The initial performance period for the pay-for-reporting performance requirement will consist of July 1, 2015 through June 30, 2016. Prior to and during this performance period, we will schedule multiple Open Door Forums and webinars to educate HHA personnel about the pay-for-reporting performance requirement program and the pay-for-

[26] The state-based OASIS submission system is scheduled to shut down permanently at 6:00 p.m. on December 26, 2014. Beginning at 12:00 a.m. midnight on January 1, 2015, HHAs must begin to submit their OASIS assessment via the national ASAP system. With the implementation of the ASAP system, HHAs will no longer submit OASIS assessment data to CMS via their state databases.

reporting performance QAO metric. Additionally, OASIS Education Coordinators (OECs) will be trained to provide state-level instruction on this program and metric. We have already posted a report which provides a detailed explanation of the methodology for this pay-for-reporting QAO methodology. To view this report, go to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html.* Training announcements and additional educational information related to the pay-for-reporting Performance Requirement will be provided in the near future on the HH Quality Initiatives Web page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html*).

Comment: Another commenter expressed an opinion that the terms of our proposed ''pay-for reporting performance requirement'' reporting are not clear. This commenter states the opinion that the definitions of both the numerator and the denominator in the proposed ratio are not clear.

Response: We have posted a technical report which provides a detailed explanation of the methodology used for the pay-for-reporting QAO methodology. This report provides a detailed definition of both the numerator and denominator of the QAO metric, and also addresses the definition of quality vs. non quality assessments. In addition, this report provides an extensive analysis of the pay-for reporting methodology using 2012–2013 OASIS assessment data. To view this report, go to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Pay-for-Reporting-Quality-Assessments-Only-Methodology.pdf.*

Comment: A commenter believes that it is not necessary for CMS to establish a minimum threshold for the submission of OASIS quality data because state surveyors have access to the OASIS data and, therefore, have ways to ensure HHAs are in compliance with OASIS data submission requirements.

Response: We respectfully disagree with this commenter. State surveyors would not be able to ensure compliance with the OASIS data submission requirements for several reasons. First, state surveyors have limited access to the OASIS data. Second, state surveyors do not have access to the claims/billing information that is necessary to determine if complete quality episodes have been submitted for each patient. Third, compliance with OASIS quality reporting requirements must be assessed on an annual basis in order to determine whether an HHA will receive their full market basket update or the 2 percentage point reduction for non-compliance. Therefore, use of state surveyors to perform this task is not possible.

Comment: A commenter recommended that CMS provide HHAs with a 30-day period in which to review CMS's assessment of their compliance and submit corrections if necessary.

Response: Such a process has been in place for the HH QRP for some time. This process is referred to as the ''reconsideration process.''

The OASIS data collection period runs from July 1st each year to June 30th of the following year. At the conclusion of each reporting period, we will assess the type and amount of OASIS data submitted by each HHA during the reporting period to determine whether each provider met the quality reporting requirements. HHAs that do not meet the requirements for that reporting period will be sent a ''notice of non-compliance'' letter by their Medicare Administrative Contractor (MAC). A HHA will have 30 days from the date of the ''notice of non-compliance'' letter to file a request for reconsideration to us. The HHA must tell us why they think the finding of non-compliance was incorrect and provide any documentation that proves they did meet the reporting requirements for that reporting period.

The reconsideration process can also serve to provide notice to HHAs who fall below the pay-for-reporting performance requirement for a given reporting period of their OASIS compliance score for the reporting period. The HHA will then have 30 days to submit a request for reconsideration if they disagree with the compliance score provided by us. The HHA will also have the opportunity to submit evidence on their behalf of a higher compliance score.

Comment: A commenter suggested that CMS should include an exemption from the OASIS minimum reporting requirements for small agencies similar to that given with the HH–CAHPS requirements.

Response: Small HHAs are exempt from reporting HHCAHPS for several reasons. First, the data is not collected using OASIS, but is instead collected by the HHCAHPS, which is a non-payment related data collection instrument. Second, HHCAHPS data are collected for the purpose for quality monitoring. If data were collected from very small HHAs, there is a high probability that protected patient information or confidential information could be identified simply because of the small number of responses. Therefore, the granting of an exemption to small HHAs is done to protect the integrity of the data.

However, the reporting of OASIS assessment data on each patient by HHAs is mandated by section 1895(b)(3)(B)(v)(II) of the Act. This statute required that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.'' Section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with sub clause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.''

None of the statutes or Medicare regulations related to OASIS reporting exempt small HHAs from the OASIS reporting requirements. In fact, we would not be able to provide such an exemption, as submission of OASIS assessments is a condition of payment and condition of participation in the Medicare program. Any HHA (regardless of size) that wants to bill for HH care of a Medicare patient must submit the proper OASIS assessments in order to file valid claims. Also, any HHA (regardless of size) that wants to participate in the Medicare program, must submit the required type and amount of OASIS assessments for their Medicare patients.

Comment: One commenter, though in agreement with the timeframes and the minimum scores proposed by CMS, expressed a belief that CMS should establish a disaster/exceptional circumstances policy to address situations beyond the control of the HHA that could result in the inability to submit OASIS data in a timely manner. This commenter noted that such a policy has been established in other post-acute care settings.

Response: We thank this commenter for their support of our proposal to establish a pay-for-reporting performance requirement. However, the commenter's suggestion that CMS establish an exceptional circumstances/disaster waiver policy for the HH QRP is outside the scope of the proposals that made in the proposed rule and

therefore, we are unable to comment on this suggestion. We will however take this suggestion under advisement.

Comment: One commenter expressed concern that the proposal to establish a ''pay-for-reporting'' performance requirement for OASIS reporting is actually based on a ''pay for performance'' model.

Response: The ''pay-for-reporting performance requirement'' discussed above is not a pay-for-performance model. This performance requirement simply sets a standard for the type and minimum number of OASIS assessments that each HHA must submit during a 12 month reporting period. If a HHA submits the required number of OASIS assessments during the 12 month reporting period, they will receive their full market basket update for the following calendar year.

Final Decision: After consideration of the public comments received, we are adopting as final, our proposal to establish a pay-for-reporting performance requirement, with the modifications stated below:

- For episodes beginning on or after July 1st, 2015 and before June 30th, 2016, HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement or be subject to a 2 percentage point reduction to their market basket update for CY 2017.
- We defer for now from setting a minimum OASIS reporting requirement for the 2nd and subsequent years of the OASIS ''pay-for-reporting'' performance requirement program. However, we will consider increasing the requirement in subsequent years. We anticipate rates of at least 80 percent or higher, not exceed 90 percent, in years 2 and 3.

d. Updates to HH QRP Measures Which Are Made as a Result of Review by the NQF Process

In the proposed rule, we noted that section 1895(b)(3)(B)(v)(II) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[27]

The NQF undertakes to: (1) Review new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) provide for annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) provide for measure maintenance endorsement on a 3-year cycle; (4) conduct a required follow-up review of measures with time limited endorsement for consideration of full endorsement; and (5) conduct ad hoc reviews of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review. In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. With respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We proposed that, in the event that the NQF makes updates to an endorsed measure that we have adopted for the HH QRP in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we stated that we would revise the information that is posted on the CMS Home Health Quality Initiatives Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html* so that it clearly identifies the updates and provides links to where additional information on the updates can be found. We also stated that we would refer HHAs to the NQF Web site for the most up-to date information about the quality measures (*http://www.qualityforum.org/*). In addition, we stated that we would provide sufficient lead time for HHAs to implement the changes where changes to the data collection systems would be necessary.

We further proposed to use the traditional ''notice and comment'' rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. We believed that our proposal adequately balances our need to incorporate NQF updates to NQF endorsed measures used in the HH QRP in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

We noted that a similar policy was adopted for the Hospital IQR Program, the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

We invited public comment on our proposal to adopt a policy in which NQF changes to a measure that are non-substantive in nature will be adopted using a sub-regulatory process and NQF

[27] For more information about the NQF Consensus Development Process, please visit the NQF Web site using the following link: *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx*.

changes that are substantive in nature will be adopted through the rulemaking process. We received the following public comments in response to this proposal:

Comment: One commenter was opposed to our proposal to use sub-regulatory guidance to incorporate NQF updates to previously endorsed measures unless NQF itself, in communication accompanying such updates, affirms that such updates do not substantially change the nature of the measure.

Response: We believe it unlikely that NQF will undertake to make a determination as to whether a change to a measure is substantive or non-substantive. This is a policy determination that NQF is likely to leave to the discretion of the measure steward. In the event that a measure that has been previously adopted for use in the HH QRP is updated in a manner that we determine to be non-substantive in nature, we will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. The NQF process requires an ad-hoc review of any measures that undergo substantive changes, and any party may request such an ad hoc review. If stakeholders believe a change to measures is substantive, they are encouraged to participate in the NQF process.

Comment: Several commenters expressed a concern that the definition of what changes are considered to substantive and what changes are non-substantive is not clear.

Response: As noted above, with respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

Comment: One commenter expressed the opinion that CMS should develop a more comprehensive list of substantive and non-substantive change in a measure, and further suggested that stakeholders should be given the opportunity to submit comments on the list for CMS to consider.

Response: We appreciate the commenters request for a more comprehensive list of substantive and non- substantive change in a measure, and the opportunity to submit comments on such lists. However, as noted above, we believe that our proposal adequately balances our need to incorporate NQF updates to NQF endorsed measures used in the HH QRP in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We noted that a similar policy was adopted for the Hospital Inpatient Quality Reporting (IQR) Program, the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

Comment: A commenter expressed concern that most HH providers are not aware of the NQF Consensus Development process, and therefore may not have the opportunity to comment on changes to measures.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in updates to the NQF-endorsed measures. HHAs can go to the NQF Web page for information about the measure endorsement process. The NQF process is open to the public and transparent and incorporates an opportunity for public comment and engagement in the measure maintenance process.

In the event that any measure that has been previously adopted for use in the HH QRP is updated through the NQF process, we will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. Some of the methods that we will use to keep our stakeholders informed include: (1) Posting of information on the HH Quality Initiatives Web page; (2) holding special open door forums; (3) posting information in the CMS weekly E-News publication; and (4) responding to provider questions. While we expect to provide notice to stakeholders when we intend to seek NQF's review of measures, the NQF process also incorporates an opportunity for public comment and engagement in the measure maintenance process.

Comment: Another commenter recommended that CMS notify HH providers when NQF, in their Consensus Development Process, is asking for input on NQF-endorsed measures used by HHAs, in order to give them an opportunity to comment on a change in the measure.

Response: We anticipate that in most cases such changes will occur, not during the measure development process, but after a measure has already been endorsed by NQF and has been adopted for use in the HH QRP. Changes to adopted measures could take place during yearly measure maintenance or during the 3 year measure review process.

We acknowledge that the NQF post-endorsement reviews may provide limited opportunity for provider engagement in the process. Therefore, we will make every effort to keep stakeholders informed about reviews to HH quality measures. Some of the methods that we will use to keep our stakeholders informed include: (1) Posting of information on the HH Quality Initiatives Web page; (2) holding special open door forums; (3) posting information in the CMS weekly E-News publication; and (4) responding to provider questions.

Comment: One commenter expressed the concern about whether changes labeled as non-substantive changes are truly ''non-substantive''. This commenter proposed that CMS convene a panel of HH experts, drawn from individuals representing various regions of the country and types of agencies (urban, rural, profit, non-profit, governmental, etc.) with experience in the industry, to offer their opinion on whether changes to a measure are truly ''non-substantive'' in nature. The commenter further suggested that the panel be allowed to consider the changes for ''two cycles of consideration'' and if the panel supports the changes, then the sub-regulatory could be used.

Response: In the proposed rule, we proposed to establish a policy that ''in the event that the NQF makes updates to an endorsed measure that we have adopted for the HH QRP in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications that apply to the program.'' It is our intent that this policy apply to existing NQF-endorsed quality measures that have already been adopted for use in the HH QRP. These measures have undergone the measure

development and endorsement process which typically includes multiple opportunities for input from stakeholders. Examples of stakeholder involvement include, but are not limited to: (1) Expert opinions obtained from a technical expert panel consisting of experts drawn from the HH community, (2) public comments solicited during the measure development process, and (3) multiple opportunities to provide input during the NQF endorsement process. HHAs will have multiple opportunities to become familiar with and provide their input related to the existing HH quality measures by the time they come up for the NQF one year measure maintenance review or the 3 year re-endorsement review.

Because the NQF process is open and transparent and readily available to HHAs, they can learn of possible changes existing HH quality measure as a result of the NQF process and provide their input should they choose to do so. Furthermore, the NQF process provides for a comprehensive and in-depth review of all quality measures under review (including changes to these measures) by a highly qualified panel of experts in the field of home health care. For these reasons, we do not believe it is necessary to convene another panel of home health experts, as suggested by this commenter, to seek an opinion on whether changes to a measure are truly ''non-substantive'' in nature.

This commenter further suggested that the expert panel be allowed to consider the changes for ''two cycles of consideration'' and if the panel supports the changes, then the sub-regulatory process should be used. It is not clear how this commenter defines ''two cycles of consideration'', however, it is not feasible for CMS to allow a decision regarding changes to an existing quality measure to go unresolved for a prolonged period of time. It is necessary for CMS to immediately assess any changes made to existing quality measures to determine if changes to the data collection process, data collection instrument, or technical specifications must be made. In addition CMS must determine if provider training or educational materials are required.

Final Decision: After consideration of the public comments we received, we are adopting final a policy to: (1) Utilize a sub-regulatory process to incorporate updates to the HH QRP quality measures that are not substantive in nature; and (2) continue use of the rulemaking process to adopt changes to measures that we consider to be substantive in nature.

e. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2014 HH PPS final rule (78 FR 72294), we stated that the HH quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the CY 2014 APU. We are continuing to maintain the stated HHCAHPS data requirements for CY 2015 that have been set out in CY 2014 and in previous rules. We note that home health agencies and HHCAHPS survey vendors sometimes refer to the Home Health Care CAHPS® Survey as ''HH–CAHPS'' rather than ''HHCAHPS''.

(1) Background and Description of HHCAHPS

As part of the HHS Transparency Initiative, we implemented a process to measure and publicly report patient experiences with home health care, using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the NQF in March 2009 (NQF Number 0517). The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS® (HHCAHPS) survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care.

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

For public reporting purposes, we report five measures from the HHCAHPS Survey—three composite measures and two global ratings of care that are derived from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across HHAs. We update the HHCAHPS data on Home Health Compare on *www.medicare.gov* quarterly. Each HHCAHPS composite measure consists of four or more individual survey items regarding one of the following related topics:

- Patient care (Q9, Q16, Q19, and Q24);
- Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23); and
- Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14).

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

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

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

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

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

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies also must provide on a monthly basis a list of their patients served to their respective HHCAHPS survey vendors. Agencies are not allowed to influence at all how their patients respond to the HHCAHPS survey.

As previously required, HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org.*

(2) HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.* As stated in previous HH PPS final rules, all HHCAHPS approved survey vendors must develop a Quality Assurance Plan (QAP) for survey administration in accordance with the *HHCAHPS Protocols and Guidelines Manual.* An HHCAHPS survey vendor's first QAP must be submitted within 6 weeks of the data submission deadline date after the vendor's first quarterly data submission. The QAP must be updated and submitted annually thereafter and at any time that changes occur in staff or vendor capabilities or systems. A model QAP is included in the *HHCAHPS Protocols and Guidelines Manual.* The QAP must include the following:

- Organizational Background and Staff Experience;
- Work Plan;
- Sampling Plan;
- Survey Implementation Plan;
- Data Security, Confidentiality and Privacy Plan; and
- Questionnaire Attachments

As part of the oversight activities, the HHCAHPS Survey Coordination Team conducts on-site visits to all approved HHCAHPS survey vendors. The purpose of the site visits is to allow the HHCAHPS Survey Coordination Team to observe the entire HHCAHPS Survey implementation process, from the sampling stage through file preparation and submission, as well as to assess data security and storage. The HHCAHPS Survey Coordination Team reviews the HHCAHPS survey vendor's survey systems, and assesses administration protocols based on the *HHCAHPS Protocols and Guidelines Manual* posted at *https://homehealthcahps.org.* The systems and program site visit review includes, but is not limited to the following:

- Survey management and data systems;
- Printing and mailing materials and facilities;
- Telephone call center facilities;
- Data receipt, entry and storage facilities; and
- Written documentation of survey processes.

After the site visits, HHCAHPS survey vendors are given a defined time period in which to correct any identified issues and provide follow-up documentation of corrections for review. HHCAHPS survey vendors are subject to follow-up site visits on an as-needed basis.

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

(3) HHCAHPS Requirements for the CY 2015 APU

In the CY 2014 HH PPS final rule (78 FR 72294), we stated that for the CY 2015 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for CY 2015 APU includes the second quarter 2013 through the first quarter 2014 (the months of April 2013 through March 2014). Although these dates are past, we included them in the proposed rule so that HHAs were reminded of what months constituted the requirements for the CY 2015 APU. HHAs were required to submit their HHCAHPS data files to the HHCAHPS Data Center for the HHCAHPS data from the first quarter of 2014 data by 11:59 p.m., e.d.t. on July 16, 2014.

(4) HHCAHPS Requirements for the CY 2016 APU

For the CY 2016 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for the CY 2016 APU includes the second quarter 2014 through the first quarter 2015 (the months of April 2014 through March 2015). We are in this data collection period now. HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2014 by 11:59 p.m., e.d.t. on October 16, 2014; for the third quarter 2014 by 11:59 p.m., e.s.t. on January 15, 2015; for the fourth quarter 2014 by 11:59 p.m., e.d.t. on April 16, 2015; and for the first quarter 2015 by 11:59 p.m., e.d.t. on July 16, 2015. These deadlines are firm; no exceptions are permitted.

We exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2013 through March 31, 2014) on or after April 1, 2014, from the full HHCAHPS reporting requirement for the CY 2016 APU, because these HHAs are not Medicare-certified throughout the period of April 1, 2013, through March 31, 2014. These HHAs do not need to complete a HHCAHPS Participation Exemption Request form for the CY 2016 APU.

We require that all HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2013 through March 31, 2014 request an exemption from the HHCAHPS data collection and submission requirements for the CY 2016 APU by completing the CY 2016 HHCAHPS Participation Exemption Request form. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2013, through March 31, 2014, are required to submit their patient counts on the HHCAHPS Participation Exemption Request form for the CY 2016 APU posted on *https://homehealthcahps.org* from April 1, 2014, to 11:59 p.m., e.s.t. on March 31, 2015. This deadline for the exemption form is firm, as are all of the quarterly data submission deadlines.

(5) HHCAHPS Requirements for the CY 2017 APU

For the CY 2017 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for the CY 2017 APU includes the second quarter 2015 through the first quarter 2016 (the months of April 2015 through March 2016). HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2015 by 11:59 p.m., e.d.t. on October 15, 2015; for the third quarter 2015 by 11:59 p.m., e.s.t. on January 21, 2016; for the fourth quarter 2015 by 11:59 p.m., e.d.t. on April 21, 2016; and for the first quarter 2016 by 11:59 p.m., e.d.t. on July 21, 2016. These deadlines are firm; no exceptions are permitted.

We exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2014 through March 31, 2015) on or after April 1, 2015, from the full HHCAHPS reporting requirement for the CY 2016 APU, because these HHAs are not Medicare-certified throughout the period of April 1, 2014, through March 31, 2015. These HHAs do not need to complete a CY 2017 HHCAHPS Participation Exemption Request form.

We require that all HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the

period of April 1, 2014, through March 31, 2015 request an exemption from the HHCAHPS data collection and submission requirements for the CY 2017 APU by completing the CY 2017 HHCAHPS Participation Exemption Request form. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are required to submit their patient counts on the CY 2017 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2015, to 11:59 p.m., e.s.t. on March 31, 2016. This deadline for the exemption form is firm, as are all of the quarterly data submission deadlines.

(6) HHCAHPS Reconsiderations and Appeals Process

HHAs should always monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org.* This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We continue HHCAHPS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 6704, 67164), we codified the current guideline that all approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

We continue the HHCAHPS reconsiderations and appeals process that we have finalized and that we have used for all prior periods cited in the previous rules, and utilized in the CY 2012 through CY2014 annual payment update recommendations and determinations. We have described the HHCAHPS reconsiderations and appeals process requirements in the Technical Direction Letter that we send to the affected HHAs annually in September. HHAs have 30 days from their receipt of the Technical Direction Letter informing them that they did not meet the HHCAHPS requirements to reply to CMS with documentation that supports their requests for reconsideration of the annual payment update to CMS. It is important that the affected HHAs send in comprehensive information in their reconsideration letter/package because we will not contact the affected HHAs to request additional information or to clarify incomplete or inconclusive information. If clear evidence to support a finding of compliance is not present, then the 2 percent reduction in the APU will be upheld. If clear evidence of compliance is present, then the 2 percent reduction for the APU will be reversed. We will notify affected HHAs by December 31st of the decisions that affect payments in the annual year beginning on January 1st. If we determine to uphold the 2 percent reduction for the annual payment update, the affected HHA may further appeal the 2 percent reduction via the Provider Reimbursement Review Board (PRRB) appeals process, which is described in the December letter.

The following is a summary of the comments we received regarding HHCAHPS:

Comment: A commenter stated that HHCAHPS is an unfunded administrative mandate that entails financial and resource burdens to HHAs.

Response: This comment is outside the scope of the proposed rule. We finalized the collection of HHCAHPS in the CY2014 HH PPS Final Rule published in the **Federal Register** on December 2, 2013 (78 FR 72256). Please see the comments received and our responses on pages 72295 and 72296.

Comment: A commenter stated that a more timely way of collecting and publicly reporting the HHCAHPS survey data needs to be developed.

Response: We understand this concern to collect the data in a timely manner. This is why the patients are sampled in the month following the two months of their care. We have a very strict timetable for how the 42-day survey data collection period is to be implemented, as described in the HHCAHPS Protocols and Guidelines Manual that is posted on *https://homehealthcahps.org.* We also allow time for the data received in from thousands of home health agencies to be processed and analyzed to ensure comparisons that are reliable and valid. We apply patient mix adjustment to the HHCAHPS data to allow for national comparisons. The best way to understand the reasons for our detailed survey implementation procedures is to examine the relevant sections in the *HHCAHPS Protocols and Guidelines Manual* which is posted on *https://homehealthcahps.org.*

HHAs may always request their respective HHCAHPS survey vendors to provide continual feedback on particular questions of the survey so that they are kept apprised of any issues that their patients are reporting on the HHCAHPS surveys. When HHAs contract with their vendors about the terms of their HHCAHPS data collection and processing processes, they may arrange for ways to receive survey feedback information in real-time.

Final Decision: We are not recommending any changes as a result of comments we received.

(7) For Further Information on the HHCAHPS Survey

We strongly encourage HHAs to learn about the HHCAHPS Survey and to view the official Web site for HHCAHPS at *https://homehealthcahps.org.* For further information, HHAs may also send email correspondence to the HHCAHPS Survey Coordination Team at *HHCAHPS@rti.org;* or telephone toll-free (1–866–354–0985) for more information about HHCAHPS.

3. CY 2015 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We proposed to continue this practice for CY 2015, 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 2015, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2010 and before October 1, 2011 (FY 2011 cost report data).

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

geographic designations, we provided a one-year transition in CY 2006 with a blended wage index for all sites of service. For CY 2006, the wage index for each geographic area consisted of a blend of 50 percent of the CY 2006 MSA-based wage index and 50 percent of the CY 2006 CBSA-based wage index. We referred to the blended wage index as the CY 2006 HH PPS transition wage index. As discussed in the CY 2006 HH PPS final rule (70 FR 68132), since the expiration of this one-year transition on December 31, 2006, we have used the full CBSA-based wage index values.

In the CY 2015 HH PPS proposed rule, 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, and thus, no hospital wage data on which to base the calculation of the CY 2015 HH PPS wage index. For rural areas that do not have inpatient hospitals, we would use the average wage index from all contiguous CBSAs as a reasonable proxy. For FY 2015, there are no rural geographic areas without hospitals for which we would apply this policy. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2015, the only urban area without inpatient hospital wage data is Hinesville, Georgia (CBSA 25980).

A summary of the comments we received regarding the wage index and our responses to those comments appears below. Comments on the specific proposal to use revised OMB delineations as part of the wage index are discussed further below.

Comment: A commenter is concerned about the policy for imputing a rural wage index in instances where there is no hospital. The commenter is concerned about the impact for Texas and sizable rural areas, where some rural geographic areas that almost certainly do not have an inpatient hospital, but are significant metropolitan areas such as Dallas and Houston. The commenter asserts that wage rates vary considerably in Texas between these urban and rural areas and urges CMS to be extremely cautious in this pursuit and analyze the effects of such assumptions in the methodology.

Response: As stated previously, there are currently no rural areas without hospitals. Therefore, the wage index proxy is not applicable for any rural area in CY 2015. We appreciate the comment and assure the commenter that if the need for a rural wage index proxy should arise, we would re-evaluate the policy in order to avoid possible unintended consequences. As such, we would propose any potential revision to this policy through rulemaking.

Comment: Commenters stated that hospitals have a competitive advantage in being able to apply for geographic reclassification to other CBSAs and being able to apply for the rural floor and that this creates a competitive advantage for hospitals in recruiting and retaining nurses and therapists. Commenters stated that the wage index can be very volatile with large decreases and increases in an area index value from one year to the next. Commenters stated that all provider sectors should use the same index with the same rights of reclassification, exceptions, and appeals. Commenters urged us to work with home health providers to develop regulatory and legislative remedies to the continuing problem of wage index disparity. One commenter stated that the same MSAs continue to be rewarded with higher wage indexes, while MSAs like Asheville, NC and rural NC continue to be penalized with lower wage indexes. This commenter states that the current system rewards MSAs that have inefficient and inappropriate hospital costs, and is very volatile with large decreases and increases in an MSA from one year to the next. One commenter noted that CMS is reviewing the entire wage index system and considering a move to a Commuting-Based Wage Index that would set hospital-specific wage indices. The commenter urges CMS to expedite that review and implement a system that not only recognizes variations between localities, but also treats all provider types within a local market equitably. In the meantime, commenters urge CMS to implement an immediate policy to limit the wage index variations among provider types within CBSA's and adjacent markets. Another stated that unexpected increases and decreases in wage index values should be spread over two or more years to reduce the rapid escalation or decline in wage index values and thus create more payment stability in a budget neutral fashion. The commenter specifically requests CMS respond to this broader recommendation. One commenter urged CMS to adjust the 2015 home health agency wage index to reflect a policy to limit the wage index disparity between provider types within a given CBSA to no more than 10%.

Response: Consistent with our previous responses to these recurring comments (most recently published in the CY 2014 HH PPS final rule (78 FR 72302)), the regulations 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. The rural floor provision in section 4410 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) is specific to hospitals. The reclassification provision found in section 1886(d)(10) of the Act is also specific to hospitals. CMS is exploring opportunities to reform the wage index. We refer readers to the CMS Web site at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*). We do not believe it would be appropriate to limit wage index differences or changes which are above or below a given level or to spread changes in wage index values over multiple years. The wage index values are updated annually and applying these types of changes would make the area wage index less reflective of the geographic area's wages.

Comment: A commenter believes that linking home health wage index adjustments to the pre-floor, pre-reclassified hospital wage index may have been acceptable when this index only impacted the home health payment caps under cost reimbursement that most providers never reached. However, the commenter believes that this measure is imprecise to adjust every home health payment under HHPPS and creates clear and meaningful inaccuracies. Previously, CMS responded to this comment by citing a historical precedent of 20 years ago when a home health specific wage index was proposed by CMS as part of the payment capping mechanism and was opposed by many home health agencies. The commenter requests that CMS agree to collaborate with the home health community to develop a home health specific wage index based on current data on the wage categories used in home health care today and the related costs of this labor. An additional commenter also suggested that CMS pursue a home health specific wage index. Another commenter suggested that a new wage system could be

considered for non-hospital provider sectors.

Response: Developing a wage index that utilizes data specific to HHAs would require us to engage resources in an audit process. In order to establish a home health specific wage index, we would need to collect data that is specific to home health services. This is not currently feasible due to the volatility of existing home health wage data and the significant amount of resources that would be required to improve the quality of that data. Furthermore, we believe the collection of home health specific wage data would place a significant amount of additional burden on HHAs. As discussed above, we continue to believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for the HH PPS.

Comment: A commenter expressed concern that when a hospital appeals or requests exceptions to what they believe are errors in the wage data, that corrections are not granted. The commenter asked us to reconsider this matter and believes that all providers should have the right to appeal or request exceptions when they suspect that there are errors in the data on which their rates will be based.

Response: When a hospital submits an appeal of its wage data, CMS ensures that the appeal goes through the proper protocol and is given consideration. Not every appeal will warrant being granted. When appeals are valid, CMS take immediate action to correct the wage data and publish corrections to the wage indices for all provider types.

Comment: A commenter is concerned that the home health wage index is based on inpatient hospital wage data, which in some cases contains errors that can result in significant fluctuations in the HHA wage index. Based on the Hospital Wage Index Development Timetable, there are specific deadlines for hospitals to report errors in the wage data to their MAC, CMS emphasizes that data that is incorrect in the preliminary hospital wage index data PUFs, but for which no correction request was received by the deadline, will not be changed for inclusion in the wage index. Another commenter stated that the inaction of a hospital or a mishandling of data by CMS or the MAC should not result in the lowering of an area's wage index value and, therefore, lowering Medicare payments for all HHAs in the area. Other commenters stated that inaccurate cost report data results in unpredictable year to year swings in the wage index values. Commenters are concerned that HHAs are subject to a wage index database that they have no control over. As such, HHAs are at the mercy of hospital data submission and have no means to correct erroneous data or avoid the impact of any unusual compensation changes in a hospital.

Response: We believe that the mechanisms we employ ensure the accuracy of the hospital cost report data and resulting wage index. Our contractors perform desk reviews of all hospital cost report Worksheet S–3 wage data. In addition, we perform edits on the wage data to further ensure the accuracy and validity of the wage data. Any provider may submit comments on the hospital wage index during the annual IPPS rulemaking. We believe that our review processes result in an accurate collection of wage data.

Comment: A commenter requested that CMS remove six specific counties in New Jersey from the New York City wage index.

Response: We believe that the OMB standards for delineating Metropolitan and Micropolitan Statistical Areas are appropriate for determining wage area differences. We do not believe it would be appropriate to make exceptions and carve out specific areas from the OMB delineations. The 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas were published in a **Federal Register** Notice on June 28, 2010 (75 FR 37246).

Final Decision: After considering the comments received, for the reasons discussed above and in the CY 2015 HH PPS proposed rule (79 FR 38366), we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index data to develop the HH PPS wage index. For CY 2015, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2010 and before October 1, 2011 (FY 2011 cost report data).

b. Update

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. This bulletin is available online at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* This bulletin states that it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.''

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

As discussed in the CY 2014 HH PPS final rule (78 FR 72302), the changes made by the bulletin and their ramifications required extensive review by CMS before using them for the HH PPS wage index. We completed our assessment and in the FY 2015 IPPS final rule (79 FR 49854), and stated that we will use the most recent labor market area delineations issued by OMB for payments for inpatient stays at general acute care and long-term care hospitals (LTCHs). In addition, in the FY 2015 Skilled Nursing Facility (SNF) PPS final rule (79 FR 45628), we made a final decision to use the new labor market delineations issued by OMB for payments for SNFs.

c. Implementation of New Labor Market Delineations

We believe it is important for the HH PPS to use the latest OMB delineations available to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS Web site at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*), no consensus has been achieved regarding how best to implement a replacement system. As discussed in the FY 2005 IPPS final rule (69 FR 49027), ''While we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose.'' We further believe that using the most current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and have concluded that there is no compelling reason to further delay implementation.

We proposed to incorporate the new CBSA delineations into the CY 2015 HH PPS wage index in the same manner in

which the CBSAs were first incorporated into the HH PPS wage index in CY 2006 (70 FR 68138). We proposed to use a one-year blended wage index for CY 2015. We referred to this blended wage index as the CY 2015 HH PPS transition wage index. The proposed transition wage index would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index would be calculated equal to fifty percent of the CY 2015 wage index using the old labor market area delineation and fifty percent of the CY 2015 wage index using the new labor market area delineation (both using FY 2011 hospital wage data). This ultimately results in an average of the two values.

The comments we received on the proposal to include the newest OMB area delineations into the HH PPS wage index and the proposed wage index transition methodology and our responses to these comments, appear below:

Comment: Some commenters have reservations about CMS's proposal to adopt revisions to the CBSAs developed by the Census Bureau and OMB. Commenters strongly support a phased-in approach to provide a more uniform and equitable transition for providers impacted by the CBSA revisions. Commenters believe that a phased-in approach will mitigate short-term financial instability and better align OMB's labor market areas with the actual labor costs of provider organizations.

Response: While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS Web site at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*), no consensus has been achieved regarding how best to implement a replacement system. As stated in the FY 2005 IPPS final rule (69 FR 49027), while we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose. We believe that using the most current OMB delineations would increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We believe that the most current OMB delineations accurately reflect the local economies and wage levels of the areas in which hospitals are currently located. In the CY 2015 HH PPS proposed rule, we proposed a transition period of one year, during which a 50/50 blended wage index would be used for all providers in CY 2015, in order to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. Under this proposal, providers would receive 50 percent of their FY 2015 wage index based on the new OMB delineations and 50 percent of their FY 2015 wage index based on the labor market delineations for CY 2014 (both using FY 2011 hospital wage data).

Comment: Most commenters support using a 50/50 blend of the current CBSA areas with the new CBSA areas as a way of easing the transition to the new geographic area designations. A commenter supports the budget neutrality adjustment to account for changes in the wage indices.

Response: We thank the commenters for their support of these two policies.

Comment: While a commenter commends CMS on the proposed wage index phase-in, which should afford home health providers time to adjust their budgets, expenses and operations, the commenter also recommends that home health providers that have been negatively impacted in such reclassified areas be permitted to seek a hardship exception or additional phase-in period. Such measures could be used in the event providers find that the characteristics of their operating areas remain representative of rural communities. This will help ensure that beneficiary access to home health services in such areas is not stifled or significantly negatively impacted.

Response: We do not believe that the adoption of the OMB's new area delineations will impact HHAs that provide care to beneficiaries who are located in areas whose delineations have changed to such an extent that the HHAs will no longer be able to provide care in their current locale. As always, we continue to monitor home health utilization to determine if there are any problems related to beneficiary access to care.

Comment: A commenter states that CMS' one-year transition policy of using a 50/50 blend of the previous and updated CBSA values is inconsistent with CMS' policy published in the Inpatient Prospective Payment System (IPPS) and Long- Term Acute Care Hospital-Prospective Payment System (LTCH–PPS) final rule. That rule applies a one-year 50/50 blending of the previous and updated CBSA values, respectively, only to facilities whose payments will decrease based on the use of the updated CBSAs. This inconsistency unfairly penalizes home health agencies that would benefit from applying the new CBSA delineations exclusively. Consequently, the commenter recommends that CMS apply the one-year 50/50 blend to any agencies experiencing a decrease in their payments, but utilize the new CBSA delineations for those agencies that will experience an increase in their Medicare payments. In contrast, another commenter stated that while the current requirement to maintain budget neutrality means that some agencies will not immediately see the full increases in their wage index values to reduce the impact of those with decreases, the commenter believes this is a worthwhile trade-off to assure that those agencies who would otherwise suffer sudden and significant payment declines.

Response: The implementation of the revised OMB delineations, which we are finalizing in this rule, sets home health payments at a level that more accurately reflects the costs of labor in a geographic area. Accordingly, under this policy, HHAs will experience a decrease from their current wage index only to the extent that their current wage index value actually exceeds what the latest area wage data warrants using the revised OMB delineations, and they will experience an increase from their current wage index value to the extent that their current wage index value is less than what the latest area wage data warrants using the revised OMB delineations. As discussed in the CY 2015 HH PPS proposed rule (79 FR 38416), we considered whether or not the blended wage index should be used for all HHAs or for only a subset of HHAs, such as those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations. If we were to apply the transition policy only to those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations, the wage index budget neutrality factor, discussed in section III.D.4, would result in reduced base rates for all HHAs as compared to the budget neutrality factor that results from applying the blended wage index to all HHAs. We believe that our proposal to apply a one-year blended wage index in CY 2015 for all geographic areas appropriately balances the interests of all HHAs and would best achieve our objective of providing relief to negatively impacted HHAs.

Final Decision: For the reasons previously discussed, we are finalizing our proposal to include changes to the

HH PPS wage index based on the newest OMB area delineations and to apply a one-year blended wage index in CY 2015 for all geographic areas to assist providers in adapting to these changes. This transition policy will be in effect for a one-year period, beginning January 1, 2015, and continuing through December 31, 2015. Thus, beginning January 1, 2016, the wage index for all HH PPS payments will be fully based on the new OMB delineations.

The wage index Addendum provides a crosswalk between the CY 2015 wage index using the current OMB delineations in effect in CY 2014 and the CY 2015 wage index using the revised OMB delineations. Addendum A shows each state and county and its corresponding transition wage index along with the previous CBSA number, the new CBSA number and the new CBSA name. Due to the calculation of the blended transition wage index, some CBSAs may have more than one transition wage index value associated with that CBSA. However, each county will have only one transition wage index. Therefore, for counties located in CBSAs that correspond to more than one transition wage index, a number other than the CBSA number will need to be input on the claim for CY 2015 only. These numbers are shown in the last column of Addendum A. The final CY 2015 transition wage index as set forth in Addendum A 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*

4. CY 2015 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in 42 CFR 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate 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 2015 HH PPS rates will use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and adjusted as described in section III.C. of this rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

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

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

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

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

In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus two percentage points. Any reduction of the percentage change 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 § 484.205(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 2015 National, Standardized 60-Day Episode Payment Rate

Section 1895(3)(A)(i) of the Act required that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2015 national, standardized 60-day episode payment rate, we will apply a wage index standardization factor, a case-mix budget neutrality factor described in section III.C, the rebasing adjustment described in section II.C, and the MFP-adjusted home health market basket update discussed in section III.D.1 of this final rule.

To calculate the wage index standardization factor, henceforth referred to as the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the 2015 wage index and compared it to our simulation of total payments for non-LUPA episodes using the 2014 wage index. By dividing the total payments for non-LUPA episodes using the 2015 wage index by the total payments for non-LUPA episodes using the 2014 wage index, we obtain a wage index budget neutrality factor of 1.0024. We will apply the wage index budget neutrality factor of 1.0024 to the CY 2015 national, standardized 60-day episode rate.

As discussed in section III.C of this final rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we will apply a case-mix weights budget neutrality factor to the CY 2015 national, standardized 60-day episode payment rate. The case-mix weights budget neutrality factor is calculated as the ratio of total payments when CY 2015 case-mix weights are applied to CY 2013 utilization (claims) data to total payments when CY 2014 case-mix weights are applied to CY 2013 utilization data. The case-mix budget neutrality factor for CY 2015 will be 1.0366 as described in section III.C of this final rule.

Then, we will apply the −$80.95 rebasing adjustment finalized in the CY 2014 HH PPS final rule (78 FR 72256) and discussed in section II.C. Lastly, we will update the payment rates by the CY 2015 HH payment update percentage of 2.1 percent (MFP-adjusted home health market basket update) as described in section III.D.1 of this final rule. The CY 2015 national, standardized 60-day episode payment rate will be $2,961.38 as calculated in Table 22.

TABLE 22—CY 2015 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2014 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 National, standardized 60-day episode payment
$2,869.27	×; 1.0024	×; 1.0366	−$80.95	×; 1.021	= $2,961.38

The CY 2015 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2015 HH payment update (2.1 percent) minus 2 percentage points and is shown in Table 23.

TABLE 23—FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA—CY 2015 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2014 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage minus 2 percentage points	CY 2015 National, standardized 60-day episode payment
$2,869.27	×; 1.0024	×; 1.0366	−$80.95	×; 1.001	= $2,903.37

c. National Per-Visit Rates

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

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

To calculate the CY 2015 national per-visit rates, we start with the CY 2014 national per-visit rates. We then apply a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments and increase each of the six per-visit rates by the maximum rebasing adjustments described in section II.C. of this rule. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the 2015 wage index and comparing it to simulated total payments for LUPA episodes using the 2014 wage index. By dividing the total payments for LUPA episodes using the 2015 wage index by the total payments for LUPA episodes using the 2014 wage index, we obtain a wage index budget neutrality factor of 1.0012. We will apply the wage index budget neutrality factor of 1.0012 to the CY 2015 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Finally, the per-visit rates for each discipline are updated by the CY 2015 HH payment update percentage of 2.1 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 2015 national per-visit rates are shown in Tables 24 and 25.

TABLE 24—CY 2015 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2014 Per-visit payment	Wage index budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 Per-visit payment
Home Health Aide	$54.84	×; 1.0012	+ $1.79	×; 1.021	$57.89
Medical Social Services	194.12	×; 1.0012	+ $6.34	×; 1.021	204.91
Occupational Therapy	133.30	×; 1.0012	+ $4.35	×; 1.021	140.70
Physical Therapy	132.40	×; 1.0012	+ $4.32	×; 1.021	139.75
Skilled Nursing	121.10	×; 1.0012	+ $3.96	×; 1.021	127.83
Speech-Language Pathology	143.88	×; 1.0012	+ 4.70	×; 1.021	151.88

The CY 2015 per-visit payment rates for an HHA that does not submit the required quality data are updated by the CY 2015 HH payment update (2.1 percent) minus 2 percentage points and is shown in Table 25.

TABLE 25—CY 2015 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2014 Per-visit rates	Wage index budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage minus 2 percentage points	CY 2015 Per-visit rates
Home Health Aide	$54.84	×; 1.0012	+ $1.79	×; 1.001	$56.75
Medical Social Services	194.12	×; 1.0012	+ $6.34	×; 1.001	200.89
Occupational Therapy	133.30	×; 1.0012	+ $4.35	×; 1.001	137.95
Physical Therapy	132.40	×; 1.0012	+ $4.32	×; 1.001	137.02
Skilled Nursing	121.10	×; 1.0012	+ $3.96	×; 1.001	125.33
Speech-Language Pathology	143.88	×; 1.0012	+ 4.70	×; 1.001	148.90

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

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule, we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP (78 FR 72306). We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be $235.86 (1.8451 multiplied by $127.83), subject to area wage adjustment.

e. Non-Routine Medical Supply (NRS) Conversion Factor Update

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2015 NRS conversion factor, we start with the 2014 NRS conversion factor ($53.65) and apply the −2.82 percent rebasing adjustment described in section II.C. of this rule (1 − 0.0282 = 0.9718). We then update the conversion factor by the CY 2015 HH payment update percentage (2.1 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2015 is shown in Table 26.

TABLE 26—CY 2015 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2014 NRS Conversion factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 NRS Conversion factor
$53.65	×; 0.9718	×; 1.021	= $53.23

Using the CY 2015 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 27.

TABLE 27—CY 2015 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2015 NRS Payment amounts
1	0	0.2698	$14.36
2	1 to 14	0.9742	51.86
3	15 to 27	2.6712	142.19
4	28 to 48	3.9686	211.25
5	49 to 98	6.1198	325.76
6	99+	10.5254	560.27

For HHAs that do not submit the required quality data, we again begin with the CY 2014 NRS conversion factor ($53.65) and apply the −-2.82 percent rebasing adjustment discussed in section II.C of this final rule (1 − 0.0282 = 0.9718). We then update the NRS conversion factor by the CY 2015 HH payment update percentage (2.1 percent) minus 2 percentage points. The CY 2015 NRS conversion factor for

HHAs that do not submit quality data is shown in Table 28.

TABLE 28—CY 2015 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2014 NRS conversion factor	CY 2015 rebasing adjustment	CY 2015 HH payment update percentage minus 2 percentage points	CY 2015 NRS conversion factor
$53.65	×; 0.9718	×; 1.001	$52.19

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 29.

TABLE 29—CY 2015 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2015 NRS payment amounts
1	0	0.2698	$ 14.08
2	1 to 14	0.9742	50.84
3	15 to 27	2.6712	139.41
4	28 to 48	3.9686	207.12
5	49 to 98	6.1198	319.39
6	99+	10.5254	549.32

f. Rural Add-On

Section 421(a) of the MMA required, for HH services furnished in a rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise will 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 421 of the MMA, as amended, waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

The comments we received regarding the rural add-on, along with our responses, appear below:

Comment: One commenter questioned why the rural add-on will not apply after CY 2015. Several commenter urged CMS to not eliminate the rural add-on scheduled to sunset on December 31, 2015. A commenter stated that CMS should conduct a separate and comprehensive impact analysis on what the impact of elimination of the rural-add would have in the availability of home health services in rural areas. Another commenter asked if CMS would encourage the continuation of the rural add-on for the indefinite future beyond 2016.

Response: The rural add-on is a legislative provision, mandated by the Affordable Care Act, and CMS does not have the authority to revise the date at which the rural add-on expires. Since the inception of the HH PPS, at various points in time, rural add-ons have been applied to home health payments due to legislation. These rural add-ons have not been subject to budget neutrality. If CMS were to propose a regulatory policy change to provide a rural add-on payment, we would have to apply the add-on in a budget neutral manner and adjust (decrease) other components of the payment rates.

Comment: A commenter suggests that CMS should investigate the impact of a applying a population density adjustment factor to the rates. This adjustment factor would increase payments in less densely populated areas (primarily rural) to offset higher costs of providing care in rural areas. These costs include increases in transportation costs and the scarcity of skilled professionals in rural areas. The commenter states that an increase to rural payments rates is necessary as rural wage indices are uniformly lower than urban wage indices.

Response: We do not have evidence that a population density adjustment is appropriate. While rural HHAs cite the added cost of long distance travel to provide care for their patients, urban HHAs cite added costs associated with needed security measures and traffic congestion. In regard to the commenters assertion that rural wage indices are uniformly lower than urban wage indices, our analysis shows that almost 18 percent of urban wage index values are less than the rural wage index in the corresponding state.

Comment: Commenters recommend that the rural add-on should apply for at least one year for services provided to beneficiaries in counties that are transitioning from rural to urban status for wage index purposes. Other commenters requested that CMS clarify which areas qualify for the rural add-on on as numerous areas lose rural status under the new CBSAs. Some commenters state that in 2006 when CMS blended MSA and CBSA regions as

part of a comparable wage index transition policy, CMS applied the rural add-on for both patients residing in a non-MSA and non-CBSA area. In other words, the rural add-on applied in the rural areas under the old MSA designations as well as the new CBSA designations during the transition year.

Response: When we implemented OMB revised delineations in CY 2006, we applied the rural add-on to counties in non-CBSA areas. If a county had been previously classified as rural but changed to urban classification under the new CBSAs, the rural add-on was not applied. The commenters who stated that CMS applied the rural add-on for patients residing in non-MSA areas and patients residing in non-CBSA areas are mistaken. This policy was implemented in CMS Transmittal 887 which was published on March 10, 2006. In order to remain consistent with our previous policy for applying the rural add-on, we would implement the rural add-on in the same manner for CY 2015. That is, only counties that are classified as rural under the new area delineations would receive the rural add-on. As stated previously, we believe that this method of adopting the most current OMB delineations would increase the integrity of the wage index as it is a more accurately represents geographic variation in wage levels.

Comment: One commenter recommended that CMS adopt the same definition of a ''rural'' area that is used by the Federal Office of Rural Health (ORH). The commenter states that the ORH explicitly recognizes that ''the New England states require special consideration as ''their geographic divisions are different than typical counties.'' There are many towns within Massachusetts that are very rural, yet they lie within large counties that are designated a CBSA based on the fact that there is a small city within that county. The commenter recommended that CMS modify the CBSA approach to recognize rural census tracts within large counties.

Response: In the CY 2015 HH PPS proposed rule, we did not propose alternatives to the use of CBSAs, which were adopted in the CY 2006 HH PPS final rule, to classify areas as ''rural'' for wage adjustment purposes. In the CY 2006 HH PPS final rule (70 FR 68132), we proposed and finalized the adoption of revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and core-based statistical areas (CBSAs).

Comment: A commenter requested that CMS disclose the areas that would lose their rural status under the new CBSAs.

Response: We provided several tables in the CY 2015 HH PPS proposed rule (79 FR 38392–38395) which display the counties whose status will change if we finalize our proposal to adopt the new OMB delineations. Table 13 shows the 37 counties that would change from urban to rural status. Table 14 shows the 105 counties that would change from rural to urban status. Lastly, Table 15 displays the 46 urban counties that would move from one urban CBSA to another urban CBSA.

Final Decision: For CY 2015, home health payment rates for services provided to beneficiaries in areas that are defined as rural under the new OMB delineations will be increased by 3 percent as mandated by section 3131(c) of the Affordable Care Act. The 3 percent rural add-on is applied to the national, standardized 60-day episode payment rate, national per visit rates, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. Refer to Tables 30 through 33 for these payment rates.

TABLE 30—CY 2015 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality °Data			For HHAs that DO NOT submit quality data		
CY 2015 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2015 rural national, standardized 60-day pisode payment rate	CY 2015 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2015 rural national, standardized 60-day episode payment rate
$2,961.38	×; 1.03	$3,050.22	$2,903.37	×; 1.03	$2,990.47

TABLE 31—CY 2015 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

HH Discipline type	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
	CY 2015 per-visit rate	Multiply by the 3 percent rural add-on	CY 2015 rural per-visit rates	CY 2015 per-visit rate	Multiply by the 3 percent rural add-on	CY 2015 rural per-visit rates
HH Aide	$57.89	×; 1.03	$59.63	$56.75	×; 1.03	$58.45
MSS	204.91	×; 1.03	211.06	200.89	×; 1.03	206.92
OT	140.70	×; 1.03	144.92	137.95	×; 1.03	142.09
PT	139.75	×; 1.03	143.94	137.02	×; 1.03	141.13
SN	127.83	×; 1.03	131.66	125.33	×; 1.03	129.09
SLP	151.88	×; 1.03	156.44	148.90	×; 1.03	153.37

TABLE 32—CY 2015 NRS CONVERSION FACTOR FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2015 conversion factor	Multiply by the 3 percent rural add-on	CY 2015 rural NRS conversion factor	CY 2015 Conversion factor	Multiply by the 3 percent rural add-on	CY 2015 rural NRS conversion factor
$53.23	×; 1.03	$54.83	$52.19	×; 1.03	$53.76

TABLE 33—CY 2015 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN RURAL AREAS

Severity level	Points (scoring)	For HHAs that DO submit quality data (CY 2015 NRS Conversion Factor = $54.83)		For HHAs that DO NOT submit quality data (CY 2015 NRS Conversion Factor = $53.76)	
		Relative weight	CY 2015 NRS Payment amounts for rural areas	Relative weight	CY 2015 NRS Payment amounts for rural areas
1	0	0.2698	$14.79	0.2698	$14.50
2	1 to 14	0.9742	53.42	0.9742	52.37
3	15 to 27	2.6712	146.46	2.6712	143.60
4	28 to 48	3.9686	217.60	3.9686	213.35
5	49 to 98	6.1198	335.55	6.1198	329.00
6	99+	10.5254	577.11	10.5254	565.85

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

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national, standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient care needs. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the 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 HH Resource Group (HHRG). The episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode. The outlier threshold for each case-mix group or 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 final rule (74 FR 58080 through 58087), we discussed excessive growth in outlier payments, primarily the result of unusually high outlier payments in a few areas of the country. 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 and, in the absence of corrective measures, would continue do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. To mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we adopted 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 HH expenditure). For CY 2010, we first returned 5 percent of these dollars back into 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. As amended, ''Adjustment for outliers,'' states that ''The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to HH services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to 5 percent of the total payments estimated to be made based on the prospective payment system under this subsection for the period.'' In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act, and revising it to state that the Secretary, ''subject to [a 10 percent program-specific outlier cap], may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph for a fiscal year or year may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year.''

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

2. Fixed Dollar Loss (FDL) Ratio and Loss-Sharing 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.

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

For this final rule, simulating payments using more complete CY 2013 claims data (as of June 30, 2014 rather than preliminary data as of December 31, 2013) and the CY 2014 payment rates (78 FR 72304 through 72308), we estimate that outlier payments in CY 2014 would comprise 2.00 percent of total payments. Based on simulations using CY 2013 claims data and the CY 2015 payments rates in section III.D.4 of this final rule, we estimate that outlier payments will comprise approximately 2.25 percent of total HH PPS payments in CY 2015.

Given the increases to the CY 2015 national per-visit payment rates and the national, standardized 60-day episode payment rate as a result of making the case-mix recalibration in section III.C budget neutral, our analysis estimates an additional 0.25 percentage point increase in outlier payments as a percent of total HH PPS payments each year that we phase-in the rebasing adjustments described in the background (section II.C). We estimate that by CY 2016 outlier payments as a percent of total HH PPS payments will be approximately 2.5 percent. We did not propose a change to the FDL ratio or loss-sharing ratio for CY 2015 as we believed that maintaining an FDL of 0.45 and a loss-sharing ratio of 0.80 are appropriate given the percentage of outlier payments is estimated to increase as a result of the increasing the national per-visit amounts through the rebasing adjustments. We will continue to monitor the percent of total HH PPS payments paid as outlier payments to determine if future adjustments to either the FDL ratio or loss-sharing ratio are warranted.

Although we did not propose any changes to the outlier policy, the following is a summary of the comments we received regarding outlier payments.

Comment: Several commenters stated that estimated outlier payments as a percent of total payments for CY 2015 is below the 'budgeted' amount of 2.5 percent, which has 'deprived' an appropriate level of payment for those HHAs that field high-cost cases (including cases for beneficiaries in very rural areas). These commenters further suggest that the FDL ratio and/or loss-sharing ratio should be modified so that estimated outlier payments as a percent of total payments would reach 2.5 percent.

Response: We did not propose a change to the FDL ratio for CY 2015 given the finalized increases to the CY 2015 national per-visit payment rates, which our analysis estimates will yield an additional 0.25 percentage point increase in estimated outlier payments as a percent of total HH PPS payments each year that we phase-in the rebasing adjustments described in section II.C. We estimate that for CY 2016, estimated outlier payments as a percent of total HH PPS payments will increase to 2.5 percent. We note that per section 1895(b)(5)(A) of the Act, outlier payments as a percent of total HH PPS payments ''may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year''. The statute does not require us to pay out 2.5 percent of total HH PPS payments as outlier payments; it requires us to pay no more than 2.5 percent of total HH PPS payments as outlier payments.

Additionally, we noted that these estimates do not take in to account any changes in utilization that may have occurred in CY 2014, and will continue to occur in CY 2015. We are concerned that if we decreased the FDL ratio we could potentially pay more than 2.5 percent of estimated total payments as outlier payments and that episodes without unusual variations in the type or amount of medically-necessary care will qualify for outlier payments, which is contrary to the intent of the policy. Moreover, we remain committed to addressing potentially fraudulent activities, especially those in areas where we suspect suspicious outlier payments (74 FR 58085). We believe that maintaining the current thresholds supports our prudent approach in light of such studies as those conducted by the Office of Inspector General (August 2013 Management Implications Report). We continue to examine potential revisions to the outlier payment methodology through the current contract with Abt Associates and will make recommendations and revisions if necessary.

Consequently, for the above stated reasons, we believe that we should not make any changes/revisions to our outlier payment methodology at this time.

Comment: One commenter recommended that CMS eliminate outlier payments in their entirety and return the 2.5 percent withhold to the base payment rates.

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. We plan to continue investigating 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 without qualifying episodes of care that do not meet that criteria or are potentially fraudulent. We recently awarded a contract to Abt Associates to address any findings from the home health study required by section 3131(d) of the Affordable Care Act, monitor the potential impact of the rebasing adjustments and other recent payment changes, and develop payment options to ensure ongoing access to care for vulnerable populations. The work may include potential revisions to the outlier payment methodology to better reflect costs of treating Medicare beneficiaries with high levels of severity of illness.

Comment: Several commenters stated that CMS's oversight and monitoring of insulin injection-based outlier episodes will drive outlier payments down as well as cause incorrect projections for future outlier payment.

Response: As we have noted in the past (74 FR 58085), we are committed to addressing potentially fraudulent activities, especially those in areas where we see suspicious outlier

payments. As we noted above, we plan to examine potential revisions to the outlier payment methodology through ongoing studies and analysis of home health claims and other utilization data. Monitoring of potentially fraudulent activity will be captured in this analysis, and we will make policy and other adjustments as necessary in light of the new data and outcomes.

Comment: One commenter recommended that CMS calculate outlier payments based on actual costs rather than imputed costs.

Response: Currently, an HHA episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode, and the outlier payment is defined to be an estimate of the proportion of the wage-adjusted cost beyond the wage-adjusted threshold. We believe that this estimate serves as a valid proxy for the additional costs incurred by providers. However, in an effort to further the agency's mission of providing accurate payment, we continue to evaluate the effectiveness of the current outlier payment policy approach and are considering the investigation of alternative, cost-oriented mechanisms for determining the outlier payment amount for HHA providers for those episodes that incur unusually high costs due to patient care needs.

Comment: One commenter questioned CMS's current outlier approach, which removes 5 percent from the payment rates, and then pays out 2.5 percent in outlier payments. Additionally, the commenter wanted to understand what was done with the other 2.5 percent that is no longer being paid to providers.

Response: Per section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act, CMS is required to reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. This provision is a statutory requirement and thus we do not have the authority to rescind this policy. Consequently, to implement this particular Affordable Care Act provision, CMS reduced the standardized 60-day episode payment amount by 5 percent, and set the FDL ratio such that it would target up to 2.5 percent of total estimated HH PPS payments as outlier payments.

Final Decision: We are finalizing no change to the FDL ratio or loss sharing ratio for CY 2015. 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 due to patient care needs without qualifying episodes of care that do not meet that criteria.

F. Medicare Coverage of Insulin Injections Under the HH PPS

Home health policy regarding coverage of home health visits for the sole purpose of insulin injections is limited to patients that are physically or mentally unable to self-inject and there is no other person who is able and willing to inject the patient.[28] However, the Office of Inspector General concluded in August 2013 that some previously covered home health visits for the sole purpose of insulin injections were unnecessary because the patient was physically and mentally able to self-inject.[29] In addition, results from analysis in response to public comments on the CY 2014 HH PPS final rule found that episodes that qualify for outlier payments in excess of $10,000 had, on average, 160 skilled nursing visits in a 60-day episode of care with 95 percent of the episodes listing a primary diagnosis of diabetes or long-term use of insulin (78 FR 72310). Therefore, we conducted a literature review regarding generally accepted clinical management practices for diabetic patients and conducted further analysis of home health claims data to investigate the extent to which episodes with visits likely for the sole purpose of insulin injections are in fact limited to patients that are physically or mentally unable to self-inject.

As generally accepted by the medical community, older patients (age 65 and older) are more likely to have impairments in dexterity, cognition, vision, and hearing.[30] While studies have shown that most elderly patients starting or continuing on insulin can inject themselves, these conditions may affect the elderly individual's ability to self-inject insulin. It is clinically essential that there is careful assessment prior to the initiation of home care, and throughout the course of treatment, regarding the patient's capacity for self-injection. There are multiple reliable and validated assessment tools that may be used to assess the elderly individual's ability to self-inject. These tools assess the individual's ability to perform activities of daily living (ADLs), as well as, cognitive, functional, and behavioral status.[31] These assessment tools have also proved valid for judging patients' ability to inject insulin independently and to recognize and deal with hypoglycemia.[32]

Another important consideration with regard to insulin administration in the elderly population is the possibility of dosing errors.[33] Correct administration and accurate dosing is important in order to prevent serious complications, such as hypoglycemia and hyperglycemia. The traditional vial and syringe method of insulin administration involves several steps, including injecting air into the vial, drawing an amount out of the vial into a syringe with small measuring increments, and verifying the correct dose visually.[34] In some cases, an insulin pen can be used as an alternative to the traditional vial and syringe method.

Insulin pens are designed to facilitate easy self-administration, the possession of which would suggest the ability to self-inject. Additionally, insulin pens often come pre-filled with insulin or must be used with a pre-filled cartridge thus potentially negating the need for skilled nursing for the purpose of calculating and filling appropriate doses. It is recognized that visual impairment, joint immobility and/or pain, peripheral neuropathy, and cognitive issues may affect the ability of elderly patients to determine correct insulin dosing and injection. Our literature review indicates that insulin pen devices may be beneficial in terms of safety for elderly patients due to these visual or physical disabilities.[35] To determine whether to use a traditional vial and syringe method of insulin administration versus an insulin pen, the physician must consider and understand the advantages these devices offer over traditional vials and syringes. These advantages include:

- Convenience, as the insulin pen eliminates the need to draw up a dose;

[28] Medicare Coverage Benefit Policy Manual (Pub. 100–02), Section 40.1.2.4.B.2 ''Insulin Injections.''

[29] Levinson, Daniel R. Management Implication Report 12–0011, Unnecessary Home Health Care for Diabetic Patients.

[30] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[31] Hendra, T.J. Starting insulin therapy in elderly patients. (2012). Journal of the Royal Society of Medicine. 95(9), 453–455.

[32] Sinclair AJ, Turnbull CJ, Croxson SCM. Document of care for older people with diabetes. Postgrad Med J 1996;72: 334–8.

[33] Coscelli C, Lostia S, Lunetta M, Nosari I, Coronel GA. Safety, efficacy, acceptability of a pre-filled insulin pen in diabetic patients over 60 years old. Diabetes Research and Clinical Practice. 1995;38:173–7.[PubMed].

[34] Flemming DR. Mightier than the syringe. Am J Nurs. 2000;100:44–8.[PubMed].

[35] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

• Greater dose accuracy and reliability, especially for low doses which are often needed in the elderly;
• Sensory and auditory feedback associated with the dial mechanism on many pens may also benefit those with visual impairments;
• Pen devices are also more compact, portable and easier to grip, which may benefit those with impairments in manual dexterity; and
• Less painful injections and overall ease of use.[36]

Although pen devices are often perceived to be more costly than vialed insulin, study results indicate that elderly diabetic patients are more likely to accept pen devices and adhere to therapy, which leads to better glycemic control that decreases long-term complications and associated healthcare costs.[37] The significantly improved safety profiles of pen devices also avert costly episodes of hypoglycemia.[38] It also should be noted that most insurance plans, including Medicare Part D plans, charge the patient the same amount for a month supply of insulin in the pen device as insulin in the vial.[39] Additionally, in some cases the individual with coverage for insulin pens may have one co-pay, resulting in getting more insulin than if purchasing a vial. And, there is less waste with pens because insulin vials should be discarded after 28 days after opening. However, there may be clinical reasons for the use of the traditional vial and insulin syringe as opposed to the insulin pen, including the fact that not all insulin preparations are available via insulin pen. In such circumstances, there are multiple assistive aids and devices to facilitate self-injection of insulin for those with cognitive or functional limitations. These include: nonvisual insulin measurement devices; syringe magnifiers; needle guides; prefilled insulin syringes; and vial stabilizers to help ensure accuracy and aid in insulin delivery.[40] It is expected that providers will assess the needs, abilities, and preference of the patient requiring insulin to facilitate patient autonomy, efficiency, and safety in diabetes self-management, including the administration of insulin.

Further research regarding self-injection of insulin, whether via a vial and syringe method or insulin pen, shows that education for starting insulin and monitoring should be provided by a diabetes nurse specialist, and typically entails 5 to 10 face-to-face contacts either in the patient's home or at the diabetes clinic; these are in addition to telephone contacts to further reinforce teaching and to answer patient questions.[41] This type of assessment and education allows for patient autonomy and self-efficiency and is often a preferred mode for diabetes self-management.

In the CY 2014 HH PPS final rule (78 FR 72256), we noted that the Office of Inspector General (OIG) released a ''Management Implications Report'' in August of 2013 that concluded that there was a ''systemic weakness that results in Medicare coverage of unnecessary home health care for diabetic patients''. The OIG report noted that investigations show that the majority of beneficiaries involved in fraudulent schemes have a primary diagnosis of diabetes. The report noted that OIG Special Agents found falsified medical records documenting patients having hand tremors and poor vision preventing them from drawing insulin into a syringe, visually verifying the correct dosage, and injecting the insulin themselves, when the patients did not in fact suffer those symptoms.

In light of the OIG report, we conducted analysis and performed simulations using CY 2012 claims data and described our findings in the CY 2014 Home Health PPS Final Rule (78 FR 72310). We found that nearly 44 percent of the episodes that would qualify for outlier payments had a primary diagnosis of diabetes and 16 percent of episodes that would quality for outlier payments had a primary diagnosis of ''Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled.'' Qualifying for outlier payments should indicate an increased resource and service need. However, uncomplicated and controlled diabetes typically would be viewed as stable without clinical complications and would not warrant increased resource and service needs nor would it appear to warrant outlier payments. Our simulations estimated that approximately 81 percent of outlier payments would be paid to proprietary HHAs and that approximately two-thirds of outlier payments would be paid to HHAs located in Florida (27 percent), Texas (24 percent) and California (15 percent). We also conducted additional analyses on episodes in our simulations that would have resulted in outlier payments of over $10,000. Of note, 95 percent of episodes that would have resulted in outlier payments of over $10,000 were for patients with a primary diagnosis of diabetes or long-term use of insulin, and most were concentrated in Florida, Texas, New York, California, and Oklahoma. On average, these outlier episodes had 160 skilled nursing visits in a 60-day episode of care.[42]

Based upon the initial data analysis described above and the information found in the literature review, we conducted further data analysis with more recent home health claims and OASIS data (CY 2012 and CY 2013) to expand our understanding of the diabetic patient in the home health setting. Specifically, we investigated the extent to which beneficiaries with a diabetes-related principal diagnosis received home health services likely for the primary purpose of insulin injection assistance and whether such services were warranted by other documented medical conditions. We also analyzed the magnitude of Medicare payments associated with home health services provided to this population of interest. The analysis was conducted by Acumen, LLC because of their capacity to provide real-time claims data analysis across all parts of the Medicare program (that is, Part A, Part B, and Part D).

Our analysis began with identifying episodes for the home health diabetic population based on claims and OASIS assessments most likely to be associated with insulin injection assistance. We used the following criteria to identify the home health diabetic population of interest: (1) A diabetic condition listed as the principal/primary diagnosis on the home health claim; (2) Medicare Part A or Part B enrollment for at least three months prior to the episode and during the episode; and (3) episodes with at least 45 skilled visits. This threshold was determined based on the

[36] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

[37] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[38] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[39] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

[40] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[41] Hendra, T.J. Starting insulin therapy in elderly patients. (2012). Journal of the Royal Society of Medicine. 95(9), 453–455. *http://www.ncbi.nlm.nih.gov.*

[42] This analysis simulated payments using CY 2012 claims data and CY 2012 payment rates. The simulations did not take into account the 10-percent outlier cap. Some episodes may have qualified for outlier payments in the simulations, but were not paid accordingly if the HHA was at or over its 10 percent cap on outlier payments as a percent of total payments.

distribution in the average number and length of skilled nursing visits for episodes meeting criteria 1 and 2 above using CY 2013 home health claims data. The average number of skilled nursing visits for beneficiaries who receive at least one skilled nursing visit appeared to increase from 20 visits at the 90th percentile, to 50 visits at the 95th percentile. Additionally, the average length of a skilled nursing visit for episodes between the 90th and 95th percentiles was 37 minutes, less than half the length of visits for episode between the 75th and 90th percentiles.

Approximately 49,100 episodes met the study population criteria described above, accounting for approximately $298 million in Medicare home health payments in CY 2013. Of the 49,100 episodes of interest, 71 percent received outlier payments and, on average, there were 86 skilled nursing visits per episode. In addition, 12 percent of the episodes in the study population were for patients prescribed an insulin pen to self-inject and more than half of the episodes billed (27,439) were for claims that listed ICD–9–CM 2500x, ''Diabetes Mellitus without mention of complication'', as the principal diagnosis code. ICD–9–CM describes the code 250.0x as diabetes mellitus without mention of complications (complications can include hypo- or hyperglycemia, or manifestations classified as renal, ophthalmic, neurological, peripheral circulatory damage or neuropathy). Clinically, this code generally means that the diabetes is being well-controlled and there are no apparent complications or symptoms resulting from the diabetes. Diabetes that is controlled and without complications does not warrant intensive intervention or daily skilled nursing visits; rather, it warrants knowledge of the condition and routine monitoring.

As discussed above in this section, the traditional vial and syringe method of insulin administration is one of two methods of insulin administration (excluding the use of insulin pumps). The alternative to the traditional vial and syringe method is the use of insulin pens. It would seem to be a reasonable assumption that the possession of a prescribed insulin pen would suggest the ability to self-inject. Since insulin pens often come pre-filled with insulin or must be used with a pre-filled cartridge, we believe there would not be a need for skilled nursing for the purpose of insulin injection assistance. We expect providers to assess the needs, abilities, and preference of the patient requiring insulin to facilitate patient autonomy, efficiency, and safety in diabetes self-management, including the administration of insulin. As noted above, approximately 12 percent of the episodes in the study population with visits likely for the purpose of insulin injection assistance were for patients prescribed an insulin pen to self-inject, which would seem to not conform to our current policy that home health visits for the sole purpose of insulin injection assistance is limited to patients that are physically or mentally unable to self-inject and there is no other person who is able and willing to inject the patient.

Furthermore, we recognize that our current sub-regulatory guidance may not adequately address the method of delivery. We are considering additional guidance that may be necessary surrounding insulin injection assistance provided via a pen based upon our analyses described above. We have found that literature supports that insulin pens may reduce expenses for the patient in the form of co-pays and may increase patient adherence to their treatment plan. Therefore, we encourage physicians to consider the potential benefits derived in prescribing insulin pens, when clinically appropriate, given the patient's condition.

We also investigated whether secondary diagnosis codes listed on home health claims support that the patient, either for physical or mental reasons, cannot self-inject. Our contractor, Abt Associates, with review and clinical input from CMS clinical staff and experts, created a list of ICD–9–CM codes that indicate a patient has impairments in dexterity, cognition, vision, and/or hearing that may cause the patient to be unable to self-inject insulin. We found that 49 percent of home health episodes in our study population did not have a secondary diagnosis from that ICD–9–CM code list on the home health claim that supported that the patient was physically or mentally unable to self-inject. When examining only the initial home health episodes of our study population, we found that 67 percent of initial home health episodes with skilled nursing visits likely for insulin injections did not have a secondary diagnosis on the home health claim that supported that the patient was physically or mentally unable to self-inject. Using the same list of ICD–9–CM diagnosis codes, we examined both the secondary diagnoses on the home health claim and diagnoses on non-home health claims in the three months prior to starting home health care for initial home health episodes. We found that for initial home health episodes in our study population that the percentage of episodes that did not have a secondary diagnosis to support that the patient cannot self-inject would decrease from 67 percent to 47 percent if the home health claim included diagnoses found in other claim types during the three months prior to entering home care. We do recognize that, in spite of all of the education, assistive devices and support, there may still be those who are unable to self-inject insulin and will require ongoing skilled nursing visits for insulin administration assistance. However, there is an expectation that the physician and the HHA would clearly document detailed clinical findings and rationale as to why an individual is unable to self-inject, including the reporting of an appropriate secondary condition that supports the inability of the patient to self-inject.

As described above, a group of CMS clinicians and contractor clinicians developed a list of conditions that would support the need for ongoing home health skilled nursing visits for insulin injection assistance for instances where the patient is physically or mentally unable to self-inject and there is no able or willing caregiver to provide assistance. We expect the conditions included in Table 34 to be listed on the claim and OASIS to support the need for skilled nursing visits for insulin injection assistance.

Table 34: ICD–9–CM Diagnosis Codes That Indicate a Potential Inability to Self-Inject Insulin

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN

ICD–9–CM Code	Description
	Amputation
V49.61	Thumb Amputation Status.
V49.63	Hand Amputation Status.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
V49.64	Wrist Amputation Status.
V49.65	Below elbow amputation status.
V49.66	Above elbow amputation status.
V49.67	Shoulder amputation status.
885.0	Traumatic amputation of thumb w/o mention of complication.
885.1	Traumatic amputation of thumb w/mention of complication.
886.0	Traumatic amputation of other fingers w/o mention of complication.
886.1	Traumatic amputation of other fingers w/mention of complication.
887.0	Traumatic amputation of arm and hand, unilateral, below elbow w/o mention of complication.
887.1	Traumatic amputation of arm and hand, unilateral, below elbow, complicated.
887.2	Traumatic amputation of arm and hand, unilateral, at or above elbow w/o mention of complication.
887.3	Traumatic amputation of arm and hand, unilateral, at or above elbow, complicated.
887.4	Traumatic amputation of arm and hand, unilateral, level not specified, w/o mention of complication.
887.5	Traumatic amputation of arm and hand, unilateral, level not specified, complicated.
887.6	Traumatic amputation of arm and hand, bilateral, any level, w/o mention of complication.
887.7	Traumatic amputation of arm and hand, bilateral, any level, complicated.
	Vision
362.01	Background diabetic retinopathy.
362.50	Macular degeneration (senile) of retina unspecified.
362.51	Nonexudative senile macular degeneration of retina.
362.52	Exudative senile macular degeneration of retina.
362.53	Cystoid macular degeneration of retina.
362.54	Macular cyst hole or pseudohole of retina.
362.55	Toxic maculopathy of retina.
362.56	Macular puckering of retina.
362.57	Drusen (degenerative) of retina.
366.00	Nonsenile cataract unspecified.
366.01	Anterior subcapsular polar nonsenile cataract.
366.02	Posterior subcapsular polar nonsenile cataract.
366.03	Cortical lamellar or zonular nonsenile cataract.
366.04	Nuclear nonsenile cataract.
366.09	Other and combined forms of nonsenile cataract.
366.10	Senile cataract unspecified.
366.11	Pseudoexfoliation of lens capsule.
366.12	Incipient senile cataract.
366.13	Anterior subcapsular polar senile cataract.
366.14	Posterior subcapsular polar senile cataract.
366.15	Cortical senile cataract.
366.16	Senile nuclear sclerosis.
366.17	Total or mature cataract.
366.18	Hypermature cataract.
366.19	Other and combined forms of senile cataract.
366.20	Traumatic cataract unspecified.
366.21	Localized traumatic opacities.
366.22	Total traumatic cataract.
366.23	Partially resolved traumatic cataract.
366.8	Other cataract.
366.9	Unspecified cataract.
366.41	Diabetic cataract.
366.42	Tetanic cataract.
366.43	Myotonic cataract.
366.44	Cataract associated with other syndromes.
366.45	Toxic cataract.
366.46	Cataract associated with radiation and other physical influences.
366.50	After-cataract unspecified.
369.00	Impairment level not further specified.
369.01	Better eye: total vision impairment; lesser eye: total vision impairment.
369.10	Moderate or severe impairment, better eye, impairment level not further specified.
369.11	Better eye: severe vision impairment; lesser eye: blind not further specified.
369.13	Better eye: severe vision impairment; lesser eye: near-total vision impairment.
369.14	Better eye: severe vision impairment; lesser eye: profound vision impairment.
369.15	Better eye: moderate vision impairment; lesser eye: blind not further specified.
369.16	Better eye: moderate vision impairment; lesser eye: total vision impairment.
369.17	Better eye: moderate vision impairment; lesser eye: near-total vision impairment.
369.18	Better eye: moderate vision impairment; lesser eye: profound vision impairment.
369.20	Moderate to severe impairment; Low vision both eyes not otherwise specified.
369.21	Better eye: severe vision impairment; lesser eye; impairment not further specified.
369.22	Better eye: severe vision impairment; lesser eye: severe vision impairment.
369.23	Better eye: moderate vision impairment; lesser eye: impairment not further specified.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
369.24	Better eye: moderate vision impairment; lesser eye: severe vision impairment.
369.25	Better eye: moderate vision impairment; lesser eye: moderate vision impairment.
369.3	Unqualified visual loss both eyes.
369.4	Legal blindness as defined in U.S.A.
377.75	Cortical blindness.
379.21	Vitreous degeneration.
379.23	Vitreous hemorrhage.
	Cognitive/Behavioral
290.0	Senile dementia uncomplicated.
290.3	Senile dementia with delirium.
290.40	Vascular dementia, uncomplicated.
290.41	Vascular dementia, with delirium.
290.42	Vascular dementia, with delusions.
290.43	Vascular dementia, with depressed mood.
294.11	Dementia in conditions classified elsewhere with behavioral disturbance.
294.21	Dementia, unspecified, with behavioral disturbance.
300.29	Other isolated or specific phobias.
331.0	Alzheimer's disease.
331.11	Pick's disease.
331.19	Other frontotemporal dementia.
331.2	Senile degeneration of brain.
331.82	Dementia with lewy bodies.
	Arthritis
715.11	Osteoarthrosis localized primary involving shoulder region.
715.21	Osteoarthrosis localized secondary involving shoulder region.
715.31	Osteoarthrosis localized not specified whether primary or secondary involving shoulder region.
715.91	Osteoarthrosis unspecified whether generalized or localized involving shoulder region.
715.12	Osteoarthrosis localized primary involving upper arm.
715.22	Osteoarthrosis localized secondary involving upper arm.
715.32	Osteoarthrosis localized not specified whether primary or secondary involving upper arm.
715.92	Osteoarthrosis unspecified whether generalized or localized involving upper arm.
715.13	Osteoarthrosis localized primary involving forearm.
715.23	Osteoarthrosis localized secondary involving forearm.
715.33	Osteoarthrosis localized not specified whether primary or secondary involving forearm.
715.93	Osteoarthrosis unspecified whether generalized or localized involving forearm.
715.04	Osteoarthrosis generalized involving hand.
715.14	Osteoarthrosis localized primary involving hand.
715.24	Osteoarthrosis localized secondary involving hand.
715.34	Osteoarthrosis localized not specified whether primary or secondary involving hand.
715.94	Osteoarthrosis unspecified whether generalized or localized involving hand.
716.51	Unspecified polyarthropathy or polyarthritis involving shoulder region.
716.52	Unspecified polyarthropathy or polyarthritis involving upper arm.
716.53	Unspecified polyarthropathy or polyarthritis involving forearm.
716.54	Unspecified polyarthropathy or polyarthritis involving hand.
716.61	Unspecified monoarthritis involving shoulder region.
716.62	Unspecified monoarthritis involving upper arm.
716.63	Unspecified monoarthritis involving forearm.
716.64	Unspecified monoarthritis involving hand.
716.81	Other specified arthropathy involving shoulder region.
716.82	Other specified arthropathy involving upper arm.
716.83	Other specified arthropathy involving forearm.
716.84	Other specified arthropathy involving hand.
716.91	Unspecified arthropathy involving shoulder region.
716.92	Unspecified arthropathy involving upper arm.
716.93	Unspecified arthropathy involving forearm.
716.94	Unspecified arthropathy involving hand.
716.01	Kaschin-Beck disease shoulder region.
716.02	Kaschin-Beck disease upper arm.
716.04	Kaschin-Beck disease forarm.
716.04	Kaschin-beck disease involving hand.
719.81	Other specified disorders of joint of shoulder region.
719.82	Other specified disorders of upper arm joint.
719.83	Other specified disorders of joint, forearm.
719.84	Other specified disorders of joint, hand.
718.41	Contracture of joint of shoulder region.
718.42	Contracture of joint, upper arm.
718.43	Contracture of joint, forearm.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
718.44	Contracture of hand joint.
714.0	Rheumatoid arthritis.
	Movement Disorders
332.0	Paralysis agitans (Parkinson's).
332.1	Secondary parkinsonism.
333.1	Essential and other specified forms of tremor.
736.05	Wrist drop (acquired).
	After Effects from Stroke/Other Disorders of the Central Nervous System/Intellectual Disabilities
438.21	Hemiplegia affecting dominant side.
438.22	Hemiplegia affecting nondominant side.
342.01	Flaccid hemiplegia and hemiparesis affecting dominant side.
342.02	Flaccid hemiplegia and hemiparesis affecting nondominant side.
342.11	Spastic hemiplegia and hemiparesis affecting dominant side.
342.12	Spastic hemiplegia and hemiparesis affecting nondominant side.
438.31	Monoplegia of upper limb affecting dominant side.
438.32	Monoplegia of upper limb affecting nondominant side.
343.3	Congenital monoplegia.
344.41	Monoplegia of upper limb affecting dominant side.
344.42	Monoplegia of upper limb affecting nondominant side.
344.81	Locked-in state.
344.00	Quadriplegia unspecified.
344.01	Quadriplegia c1–c4 complete.
344.02	Quadriplegia c1 c4 incomplete.
344.03	Quadriplegia c5–c7 complete.
344.04	Quadriplegia c5–c7 incomplete.
343.0	Congenital diplegia.
343.2	Congenital quadriplegia.
344.2	Diplegia of upper limbs.
318.0	Moderate intellectual disabilities.
318.1	Severe intellectual disabilities.
318.2	Profound intellectual disabilities.

Although we did not propose any policy changes at this time, we solicited public comments on whether the conditions in Table 34 represent a comprehensive list of codes that appropriately indicate that a patient may not be able to self-inject and solicited comments on the use of insulin pens in home health. We plan to continue monitoring claims that are likely for the purpose of insulin injection assistance. Historical evidence in the medical record must support the clinical legitimacy of the secondary condition(s) and resulting disability that limit the beneficiary's ability to self-inject.

The following is a summary of the comments we received regarding our discussion of Medicare Coverage of Insulin Injections under HH PPS.

Comment: A few commenters provided additional ICD–9–CM codes that CMS should consider as supporting the need for insulin injections because a patient cannot self-inject.

Response: We thank the commenters for identifying additional ICD–9–CM codes for us to consider. The ICD–9–CM codes that were identified by the commenters will be reviewed by our clinical staff and our contractors and will be taken into consideration in developing any future sub-regulatory guidance on insulin injections.

Comment: Many commenters noted their general support of a comprehensive list of codes that appropriately indicate that a patient may not be able to self-inject. However, several commenters also suggested that CMS develop guidelines that are evidenced-based along with clinical and practical reasoning. A few commenters suggested that the evidence-based guidelines should be developed through the National Coverage Determination process, with presumptive eligibility or ineligibility, and an opportunity for the patient or HHA to rebut the presumption of ineligibility prior to denial of coverage.

Response: The list of codes included in the proposed rule was not designed to provide guidelines for determining eligibility for insulin injections during a home health episode. Rather, the list of codes was designed to identify conditions that support the need for home health skilled nursing visits for insulin injection assistance when the patient is physically or mentally unable to self-inject and there is no able or willing caregiver to provide assistance. The National Coverage Determination process describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. Under current policy, insulin injection assistance can be paid for under the Medicare home health benefit. Therefore, a National Coverage Determination is not necessary for insulin injections provided within a home health episode of care.

Comment: One commenter stated that it is sometimes difficult to specify a single condition that describes why the patient cannot self-inject. The commenter also stated that the list of codes was developed using ICD–9–CM codes, which will be obsolete in the future given the expansion of codes available under ICD–10–CM. One commenter suggested that we convene stakeholders after ICD–10–CM is implemented to determine a comprehensive list based on ICD–10–CM codes.

Response: The list of codes that appropriately indicate that a patient may not be able to self-inject was developed based on codes currently available and is aimed at assisting providers and contractors in identifying diabetic patients who may not be able self-inject insulin. The list of codes is not designed to limit the provider's ability to demonstrate the necessity for insulin injections based on other information in the medical record. We agree that there may be more codes available under ICD–10–CM and plan to appropriately crosswalk the list of ICD–9–CM codes to ICD–10-Codes. We would like to note that the ICD–9–CM codes are listed in this rule because they are currently the official code set for home health claims. In addition, convening a stakeholder panel to create a comprehensive list of ICD–10–CM codes is not necessary. Any sub-regulatory guidance issued would include this list of ICD–9–CM codes appropriately translated into ICD–10–CM codes developed using the general equivalency mapping software and the clinical judgment of our clinicians and contractor clinicians.

Comment: One commenter noted that CMS should not consider a future proposal to use a list of conditions as the single means of establishing coverage eligibility for insulin injections. Many commenters stated that any sub-regulatory guidance that identifies conditions that support a patient's inability to self-inject will result in the inaccurate denial of coverage for insulin injections thus placing the beneficiary at risk.

Response: The discussion surrounding insulin injections was included in the rule to invite public comment and gather industry input on potential sub-regulatory guidance on this issue. We did not propose that the list of codes identified in the CY 2015 HH PPS proposed and final rules would as the sole means of establishing coverage eligibility for insulin injection assistance under the Medicare home health benefit. Rather, we identified these conditions as a means for providers and contractors to identify patients who may not be able to self-inject insulin.

Comment: One commenter stated that they are concerned they will be required to ''screen'' patients and as such, the patient may not be afforded appeal rights.

Response: We will take this opportunity to remind HHAs that they are not to enroll patients that do not meet the eligibility criteria for home health services. A patient that has been determined to be ineligible by a HHA has the right to ask for a review of eligibility by the Quality Improvement Organization.

Comment: A commenter noted a concern that ''Attachment D'' does not permit the HHA to report diagnoses that do not require interventions on the OASIS (and subsequently the home health claim), thus precluding the home health agency from reporting one of these supporting diagnoses.

Response: ''Attachment D'' guidance requires that secondary diagnoses reported be addressed in the home health plan of care. The focus of this discussion surrounds home health visits for the sole purpose of insulin injections. If the patient requires home health services for the sole purpose of insulin injections, it appears logical for these services to be reported in the plan of care and require interventions that may be supported by the reporting of the appropriate diagnosis that prevents the patient from self-injecting. Additionally, ICD–9–CM and ICD–10–CM coding guidelines state ''for reporting purposes the definition for ''other diagnoses'' is interpreted as additional conditions that affect patient care in terms of requiring: Clinical evaluation; or therapeutic treatment; or diagnostic procedures; or extended length of hospital stay; or increased nursing care and/or monitoring.'' Therefore, reporting a diagnosis that supports the reason for daily nursing visits for insulin injections would be in adherence with ICD–9–CM and ICD–10–CM coding guidelines, even if that condition is not the primary reason for the home health encounter. Because that condition is affecting the home health plan of care with the need for daily skilled nursing visits for insulin injections, it would be appropriate to list that diagnosis on the OASIS as well as on the home health claim.

Comment: One commenter noted that CMS should consider a range of clinical reasons that indicate a patient may not be able to self-inject, which may or may not relate to the diagnosis associated with the current home health episode. The commenter provided an example of an amputation or a cognitive defect stemming from a prior stroke.

Response: We have not proposed a policy that limits coverage to a list of conditions that would indicate why a home health beneficiary is unable to self-inject. We recognize that there can be a wide range of reasons and multiple reasons why a beneficiary is unable to self-inject. The list of diagnoses in the CY 2015 HH PPS proposed and final rule was determined, through clinical review, to support reasons why a skilled nurse would have to administer a daily insulin injection(s). In the commenter's scenario, if an amputation or cognitive defect necessitates that a skilled nurse administer insulin injection(s), then those conditions would be related to the reason the patient needs home health care. The presence of such conditions could indicate why there is the need for the skilled nurse to provide the injection(s), even though the insulin injection itself is for the treatment and management of diabetes. If any of the diagnoses listed in the CY 2015 HH PPS proposed and final rules are the reason(s) for the inability for the beneficiary to self-inject, then it is appropriate for the home health agency to report these conditions as they would meet the ICD–9–CM and ICD–10–CM coding guidelines to report those conditions on the OASIS and home health claim. We would also note that the examples provided of an amputation or cognitive defect were included in our list of conditions that may support that a patient is unable to self-inject insulin.

We thank the commenters for providing us with their feedback and will use the information collected to inform any sub-regulatory guidance. We will also continue to monitor home health claims likely for visits to provide insulin injection assistance and we remind providers that historical evidence in the medical record must support the patient's inability to self-inject.

G. Implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM)

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 212 of the PAMA, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provides that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and § 162.1002 of title 45, Code of Federal Regulations.'' Since the release of the CY 2015 HH PPS proposed rule (79 FR 38366–38420), HHS has finalized the new compliance date for ICD–10–CM and ICD–10–PCS. The August 4, 2014 final rule titled ''Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD–10–CM and ICD–10–PCS Medical Data Code Sets'' (79 FR 45128) announced October 1, 2015 as the compliance date. Under that final rule, the transition to ICD–10–CM is required for entities covered by the Health

Insurance Portability and Accountability Act of 1996 (HIPAA)(Pub. L. 104–91, enacted on August 21, 1996). The rule also requires covered entities to continue using ICD–9 through September 30, 2015. Diagnosis reporting on home health claims must adhere to ICD–9–CM coding conventions and guidelines regarding the selection of principal diagnosis and the reporting of additional diagnoses until that time. The current ICD–9–CM Coding Guidelines refer to the use of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) and are available through the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html* or on the CDC's Web site at *http://www.cdc.gov/nchs/icd/icd9cm.htm.* We plan to disseminate more information about the transition from ICD–9–CM to ICD–10–CM through the HHA Center Web site, the Home Health, Hospice and DME Open Door Forum, and in future rulemaking.

The following is a summary of the comments we received regarding the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM).

Comment: One commenter stated that certain codes were not included in the translation list provided in last year's rule and attributed the omission to the limitations of our GEMS tool.

Response: The CY 2015 HH PPS proposed rule did not contain a discussion of the translation list. Rather, the translation list was discussed in the CY 2014 HH PPS proposed and final rules. We invite further comments on the translation list, which should be submitted via email to *grouperemail@mmm.com.* We will review the comments and provide a response.

Comment: Several commenters suggested that CMS post ICD–10–CM information and the grouper in an expedited manner to afford additional lead time to make the system changes that support ICD–10–CM submission effective October 1, 2015.

Response: We plan to adjust our schedule to provide additional lead time. The CY 2014 HH PPS final rule (77 FR 67450–67531) announced a grouper release date in July 2014, providing three months lead time when the previous implementation date was October 1, 2014. We are adjusting our scheduled to release the ICD–10–CM HH PPS Grouper on April 1, 2015, which provides six months of lead time for HHAs and vendors to prepare for the transition to an ICD–10–CM HH PPS Grouper. In addition, we are planning to conduct additional outreach activities that will be announced in the future.

As background, CMS and our support contractors, Abt Associates and 3M, spent over 2 years implementing a process for the transition from the use of ICD–9–CM diagnosis codes to ICD–10–CM diagnosis codes within the HH PPS Grouper and outlined the process in the CY 2014 HH PPS proposed and final rules. No additional changes have been identified since that time and no additional ICD–10–CM codes have been added that would cause us to revise the grouper that was designed based on the CY 2014 HH PPS final rule.

The final translation list (which includes all of the codes listed in the draft posted to the CMS Web site) will be posted to the Home Health section of the CMS Web site. A draft ICD–10–CM HH PPS Grouper will be released on or before January 1, 2015 to our vendors that have registered as beta-testers. Beta-testers are again being reminded to provide any comments or feedback within 2 weeks of receipt based upon the processed outlined on the CMS Web site. The purpose of an early release to the beta testers is to identify any significant issues early in the process. Providers who are interested in enrolling as a beta site can obtain more information on the HH PPS Grouper Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMixGrouperSoftware.html.* As we noted above, the final ICD–10–CM HH PPS Grouper will be posted via the CMS Web site by April 1, 2015. As we are providing three months of additional lead-time, providers should take advantage of this time to prepare their systems to submit ICD–10–CM codes for any services that reflect a date of October 1, 2015 and later for item M0090 on the OASIS. Item M0090 is the assessment completion date reported by the HHA on the OASIS and the grouper logic requires that any assessment with a M0090 date on or after October 1, 2015 contain ICD–10–CM codes.

H. Proposed Change to the Therapy Reassessment Timeframes

Effective January 1, 2011, therapy reassessments must be performed on or ''close to'' the 13th and 19th therapy visits and at least once every 30 days (75 FR 70372). A qualified therapist, of the corresponding discipline for the type of therapy being provided, must functionally reassess the patient using a method which would include objective measurement. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record. We anticipated that policy regarding therapy coverage and therapy reassessments would address payment vulnerabilities that have led to high use and sometimes overuse of therapy services. We also discussed our expectation that this policy change would ensure more qualified therapist involvement for beneficiaries receiving high amounts of therapy. In our CY 2013 HH PPS final rule, we provided further clarifications regarding therapy coverage and therapy reassessments (77 FR 67068). Specifically, similar to the existing requirements for therapy reassessments when the patient resides in a rural area, we finalized changes to § 409.44(c)(2)(i)(C)(*2*) and (D)(*2*) specifying that when multiple types of therapy are provided, each therapist must assess the patient after the 10th therapy visit but no later than the 13th therapy visit and after the 16th therapy visit but no later than the 19th therapy visit for the plan of care. In § 409.44(c)(2)(i)(E)(*1*), we specified that when a therapy reassessment is missed, any visits for that discipline prior to the next reassessment are non-covered.

Analysis of data from CYs 2010 through 2013 shows that the frequency of episodes with therapy visits reaching 14 and 20 therapy visits did not change substantially as a result of the therapy reassessment policy implemented in CY 2011 (see Table 35). The percentage of episodes with at least 14 covered therapy visits was 17.2 percent in CY 2010 and decreased to 16.0 percent in CY 2011. In CY 2013 the percentage of episodes with at least 14 covered therapy visits increased to 16.3 percent. Likewise, the percentage of episodes with at least 20 covered therapy visits was 6.0 percent in CY 2010 and decreased to 5.4 percent in CY 2011. In CY 2013, the percentage of episodes with at least 20 covered therapy visits was 5.3 percent. We analyzed data for specific types of providers (for example, non-profit, for profit, freestanding, facility-based), and we found the similar trends in the number of episodes with at least 14 and 20 covered therapy visits. For example, for non-profit HHAs, the percentage of episodes with at least 14 covered therapy visits decreased from 11.8 percent in CY 2010 to 11.1 in CY 2011 and episodes with at least 20 covered therapy visits decreased from 4.2 percent in CY 2010 to 3.9 percent in CY 2011. For proprietary HHAs, the percentage of episodes with at least 14 covered therapy visits decreased from 19.7 percent in CY 2010 to 18.2 percent in CY 2011 and episodes with at least 20 covered therapy visits decreased

from 6.8 percent in CY 2010 to 6.1 percent in CY 2011.

As we stated in section III.A of this final rule, in addition to the implementation of the therapy reassessment requirements in CY 2011, HHAs were also subject to the Affordable Care Act face-to-face encounter requirement, payments were reduced to account for increases nominal case-mix, and the Affordable Care Act mandated that the HH PPS payment rates be reduced by 5 percent to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments. The estimated net impact to HHAs for CY 2011 was a decrease in total HH PPS payments of 4.78 percent. The independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year. We note that in our CY 2012 HH PPS final rule (76 FR 68526), we recalibrated and reduced the HH PPS case-mix weights for episodes reaching 14 and 20 therapy visits, thereby diminishing the payment incentive for episodes at those therapy thresholds.

TABLE 35—PERCENTAGE OF EPISODES WITH 14 AND 20 THERAPY VISITS, CY 2010 THROUGH 2013

Calendar year	Episodes with at least 1 covered therapy visit	Episodes with at least 14 covered therapy visits	Episodes with at least 20 covered therapy visits
2010	54.1	17.2	6.0
2011	54.2	16.0	5.4
2012	55.2	15.6	5.2
2013	56.3	16.3	5.3

Source: CY 2010 claims from the Datalink file and CY 2011 through CY 2013 claims from the standard analytic file (SAF).
Note(s): For CY 2010, we included all episodes that began on or after January 1, 2010 and ended on or before December 31, 2010 and we included a 20% sample of episodes that began in CY 2009 but ended in CY 2010. For CY 2011 and CY 2013, we included all episodes that ended on or before December 31 of that CY (including 100% of episodes that began in the previous CY, but ended in the current CY).

Since the therapy reassessment requirements were implemented in CY 2011, providers have expressed frustration regarding the timing of reassessments for multi-discipline therapy episodes. In multiple therapy episodes, therapists must communicate when a planned visit and/or reassessment is missed to accurately track and count visits. Otherwise, therapy reassessments may be in jeopardy of not being performed during the required timeframe increasing the risk of subsequent visits being non-covered. As stated above, our recent analysis of claims data from CY 2010 through CY 2013 does not show significant change in the percentage of cases reaching the 14 therapy visit and 20 therapy visit thresholds between CY 2010 and CY 2011. Moreover, payment increases at the 14 therapy visit and 20 therapy visit thresholds have been somewhat mitigated since the recalibration of the case-mix weights in CY 2012. Therefore, we proposed to simplify § 409.44(c)(2) to require a qualified therapist (instead of an assistant) from each discipline to provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least every 14 calendar days.

The proposed requirement to perform a therapy reassessment at least once every 14 calendar days would apply to all episodes regardless of the number of therapy visits provided. All other requirements related to therapy reassessments will remain unchanged, such as a qualified therapist (instead of an assistant) from each therapy discipline provided will still be required to provide the ordered therapy service and functionally reassess the patient using a method which would include objective measurements. The measurement results and corresponding effectiveness of the therapy, or lack thereof, would be documented in the clinical record. In the proposed rule, we stated our belief that revising this requirement would make it easier and less burdensome for HHAs to track and to schedule therapy reassessments every 14 calendar days as opposed to tracking and counting therapy visits, especially for multiple-discipline therapy episodes. We also believed that this proposal would reduce the risk of non-covered visits so that therapists could focus more on providing quality care for their patients, while still promoting therapist involvement and quality treatment for all beneficiaries, regardless of the level of therapy provided.

In the CY 2015 HH PPS proposed rule (79 FR 38366–38420), we invited comment on this proposal and the associated change in the regulation at § 409.44. The following is a summary of comments we received regarding the proposed change to the therapy reassessment timeframes.

Comment: Commenters strongly supported removing the requirement to perform therapy reassessments on or ''close to'' the 13th and 19th therapy visits. Commenters appreciate our effort to simplify the therapy reassessment timeframes in order to allow more time and energy to be focused on the patients and outcomes and less time on counting visits. However, the commenters believe that the proposed reassessment interval of every 14 days would be too frequent. They noted that the 14-day interval is not linked to a clinical objective that benefits the patient. They note that changes in function as a result of improvements in functional strength, balance, and other impairments typically take longer than the 14 days. Commenters state that physiological change requires six to eight weeks to occur depending on the patient's individual goals. They believe this to be true especially in the case of home health patients who typically have complex, multi-system impairments. Most commenters believe that a 30 day reassessment would be more realistic in terms of commonly used functional tests, such as the Berg Balance test, Gait Velocity, Chair Rise test, Timed Up and Go, and Barthel Index, being able to detect a change. Several commenters believe the 14 day requirement would lead to scheduling congestion due to the shortage of qualified therapists and time constraints in rural areas where therapists spend a lot of time traveling to the patient's residence. Commenters state that this would make it exceedingly difficult for HHAs to accommodate both patient and staff scheduling needs, which would negatively impact patient care. Commenters believe that the proposed 14 day reassessment requirement discourages the proper use of assistants and their role in home health care. In addition, commenters state that the 14 day timeframe is burdensome in that it increases documentation requirements and does nothing to promote quality of

care. For example, commenters expect that the 14 day reassessment timeframe will result in patient complaints that therapists are spending too much treatment time on documentation. Additionally, the 14 day reassessment timeframe negatively impacts continuity of care. For example, if a patient is being seen by a certified occupational therapy assistant and a physical therapy assistant, then the patient would be seen by four different therapists in a two week time period. This could be overwhelming for the patient. Continuity of care and personnel are important with this population to ensure trust and follow through which directly impacts the patient's adherence to a home exercise program and to follow the functional and safety recommendations made by the treating therapists.

Several commenters stated that patient care should not be determined by a calendar and that the reassessment should still be based on the frequency of visits. Some commenters recommended that the reassessment be performed every 5th or 6th visit while others recommended that it be performed every 8th or 10th visit. However, the majority of commenters stated that converting this requirement to a calendar day based interval will be far easier to track and manage. Most commenters believe that a calendar day based interval will reduce the likelihood of inadvertently missing an assessment, especially when the patient is receiving multiple types of therapy. Several commenters suggested a reassessment timeframe in the range of every 20 to 28 days. A few commenters suggested every 6 to 8 weeks. One commenter recommended performing the assessment every 60 days. The overwhelming majority of commenters recommended reassessing the patient at least once every 30 days as the most appropriate time frame. Commenters stated that a 30 day reassessment timeframe aligns with many state practice acts, which require that a therapist reassess the patient at least once every 30 days.

Response: As a result of the comments we received, in which most commenters suggested requiring therapy reassessments at least once every 30 days, we are finalizing our proposal to eliminate the therapy reassessments that are required to be performed on or ''close to'' the 13th and 19th therapy visits. We are also finalizing that a qualified therapist (instead of an assistant) from each discipline provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least once every 30 calendar days, rather than at least every 14 calendar days, as proposed.

Comment: Some commenters suggested that we provide either a 3 or 5 day window or grace period before and after the 30th day in which to complete the reassessment.

Response: A 3–5 day window before the 30th day is built into the requirement to perform the reassessment at least once every 30 calendar days. However, we will not adopt a policy of allowing for a 3 or 5 day window or grace period after the 30th calendar day as some of the commenters suggested. We believe that requiring therapy reassessments to be performed at least once every 30 calendar days is flexible and enhances patient care.

Comment: Some commenters asked for clarification as to whether the proposed reassessment would be required at least once every 14 calendar days or exactly every 14th calendar day.

Response: We had intended that the proposed requirement would be for the reassessment to be performed at least once every 14 calendar days. We will finalize a requirement that the reassessment be performed at least once every 30 days. The reassessment will not have to be done on exactly the 30th day. For example, the reassessment could be done on the 21st day or the 28th day as clinically appropriate and deemed necessary by the therapist.

Comment: One commenter stated that it is in the best interest of the patient to have regular interaction with the actual therapist, not just the assistant. The commenter believes that assistants generally should not be routinely used in the home setting unless they have demonstrated advanced proficiencies in the setting and that assistant visits should be reimbursed at a lower level since HHAs pay them less.

Response: We believe that therapy assistants play a very important role in supporting therapists and providing care to home health patients, especially in rural areas and areas where there is a shortage of therapists. The home health Conditions of Participation (CoPs), at § 484.32, state that any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs. In addition, guidelines published by the American Physical Therapy Association (APTA) state:

> When supervising the physical therapist assistant in any off-site setting, the following requirements must be observed:
>
> 1. A physical therapist must be accessible by telecommunications to the physical therapist assistant at all times while the physical therapist assistant is treating patients/clients.
>
> 2. There must be regularly scheduled and documented conferences with the physical therapist assistant regarding patients/clients, the frequency of which is determined by the needs of the patient/client and the needs of the physical therapist assistant.
>
> 3. In those situations in which a physical therapist assistant is involved in the care of a patient/client, a supervisory visit by the physical therapist will be made:
>
> a. Upon the physical therapist assistant's request for a reexamination, when a change in the plan of care is needed, prior to any planned discharge, and in response to a change in the patient's/client's medical status.
>
> b. At least once a month, or at a higher frequency when established by the physical therapist, in accordance with the needs of the patient/client.
>
> c. A supervisory visit should include:
>
> i. An on-site reexamination of the patient/client.
>
> ii. On-site review of the plan of care with appropriate revision or termination.
>
> iii. Evaluation of need and recommendation for utilization of outside resources.''[43]

We believe that requiring therapy reassessments at least once every 30 days, the current CoP requirements, and the APTA guidelines together promote regular interaction between the therapist and the patient. We will continue to monitor the frequency of assistant visits. As shown in Table 36 below, CY 2011 through CY 2013 claims data indicates that about 30 percent of the time, physical therapy is provided by assistants and about 15 percent of the time, occupational therapy is provided by assistants.

[43] *http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Practice/DirectionSupervisionPTA.pdf.*

TABLE 36—PERCENTAGE OF VISITS PROVIDED BY A PHYSICAL THERAPY AND OCCUPATIONAL THERAPY ASSISTANTS, CY 2011 THROUGH 2013

Year	Percentage of PT visits provided by a PTA	Percentage of OT visits provided by an OTA
2011	23.8	14.4
2012	28.5	15.4
2013	29.2	15.4

Source: Analysis of CY 2011 through CY 2013 claims data from the Standard Analytic File (SAF).

Note(s): We included all episodes that ended on or before December 31 of that CY (including 100% of episodes that began in the previous CY, but ended in the current CY).

Bureau of Labor Statistics (BLS) data on wage and fringe rates is currently used along with the minutes of care provided during home health episodes, as found on claims, to calculate an episode's resource use (an estimate of the relative cost of the episode). Data on resource use is used to construct case-mix weights that adjust the base payment rate in order to more accurately pay for home health episodes. Since CY 2012, the case mix system takes into account whether visits were performed by a therapist or a therapy assistant when constructing the case mix weights by calculating an episode's resource use accordingly. The Medicare HHA cost report form may be revised in the near future, but currently the form does not allow us to differentiate the cost of a therapist visit from a therapy assistant visit. We will consider whether separate LUPA rates for therapists versus therapy assistants are needed in the future.

Comment: A commenter requested clarification regarding the semantics of our proposal ''. . . to require a qualified therapist (instead of an assistant) from each discipline to provide the needed therapy service and functionally reassess the patient . . .'' as this could be interpreted two different ways. The commenter is concerned that the language could be interpreted to mean that therapy assistants will no longer be eligible to perform visits in the home health setting.

Response: We are not changing our existing policy regarding therapy assistants. Assistants may still perform physical therapy services and occupational therapy services which they are qualified to perform. Therapy assistants may provide therapy visits as medically reasonable and necessary to treat the patient throughout the duration of the episode. As stated in our existing policy, during the visit in which the therapist performs the assessment, the qualified therapist (not a therapy assistant) must also provide the therapy service(s).

Comment: One commenter asked if the new therapy reassessment timeframe will only apply to episodes beginning on or after January 1, 2015 or if it will also apply to episodes spanning January 1, 2015.

Response: The new therapy reassessment requirement will apply to episodes that begin on or after January 1, 2015.

Comment: Several commenters questioned when the reassessment clock would start. They asked for more clarity about whether the count would begin at the start of the episode or from the date the patient is first seen by a therapist.

Response: The clock would start from the date the patient is first seen by the qualified therapist, as per § 409.44(c)(2)(i)(A) the patient's function must be initially assessed by a qualified therapist. As stated in current guidance, the reassessment clock is not measured by episode but by the patient's full course of treatment. That is, the reassessment clock starts with the therapist's first assessment/visit and continues until the patient is discharged from home health. In cases where more than one type of therapy is being provided, each therapy discipline has its own separate clock. The 30-day clock begins with the first therapy service (of that discipline) and the clock resets with each therapist's visit/assessment/measurement/documentation (of that discipline).

In order to determine when the next therapy reassessment visit by a qualified therapist would be required, as it relates to the ''at least every 30 days'' requirement, the counting should begin the day after the service is provided. For example, if a therapist conducted and documented an assessment of a patient during a visit on April 1, the count would begin on April 2. In this case, in order to fulfill the requirement of reassessing the patient at least once every 30 days, the therapist rather than an assistant, would need to return by May 1.

We note that the intent of the policy is to ensure that, at a minimum, a patient is seen by the therapist at least once every 30 days. The intent is not for a therapist to wait until the 30th day to visit a patient. A therapy reassessment visit should include providing the actual therapy service(s), functionally assessing the patient, measuring progress to determine if the goals have been met, and documenting measurement results and corresponding therapy effectiveness in the clinical record.

Comment: A commenter was supportive of a requirement for reassessing the patient every 30 days with the understanding that nothing precludes an agency from doing another assessment earlier than the 30th day if warranted by the patient's condition or ending of therapy.

Response: The commenter is correct. Nothing precludes an agency from doing another assessment earlier than the 30th day if warranted by the patient's condition or ending of therapy. As stated above, the requirement is for the qualified therapist to reassess the patient at least once every 30 days.

Comment: A commenter stated that education regarding any changes to the timing expectations is critical to reduce confusion and prevent misunderstandings and that clearly written instruction with specific examples would be extremely beneficial. The commenter further stated that partnering with the therapy associations in educational efforts will help get the correct word out to the therapists themselves.

Response: We will be updating the policy as published in chapter 7 ''Home Health Services'' of the Medicare Benefit Policy Manual (Pub. 100–20) and publishing a provider education article related to the revised policy. As always, we appreciate any educational efforts that the professional associations are able and willing to provide.

Final Decision: In summary, we are finalizing changes to the regulations at § 409.44, effective for episodes ending on or after January 1, 2015, to require that at least every 30 days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient at least every 30 days. Therapy reassessments are to be performed using a method that would include objective measurement, in accordance with accepted professional standards of clinical practice, which enables comparison of successive measurements to determine the effectiveness of therapy goals. Such objective measurements would be made by the qualified therapist using measurements which assess activities of daily living that may include but are not limited to eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, or using assistive devices, and mental and cognitive factors. The measurement results and corresponding effectiveness of the therapy, or lack

thereof, must be documented in the clinical record.

I. HHA Value-Based Purchasing Model

As we discussed previously in the FY 2009 proposed rule for Skilled Nursing Facilities (73 FR 25918, 25932, May 7, 2008), value-based purchasing (VBP) programs, in general, are intended to tie a provider's payment to its performance in such a way as to reduce inappropriate or poorly furnished care and identify and reward those who furnish quality patient care. Section 3006(b)(1) of the Affordable Care Act directed the Secretary to develop a plan to implement a VBP program for home health agencies (HHAs) and to issue an associated Report to Congress (Report). The Secretary issued that Report, which is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/downloads/stage-2-NPRM.PDF.*

The Report included a roadmap for HHA VBP implementation. The Report outlined the need to develop a HHA VBP program that aligns with other Medicare programs and coordinates incentives to improve quality. The Report indicated that a HHA VBP program should build on and refine existing quality measurement tools and processes. In addition, the Report indicated that one of the ways that such a program could link payment to quality would be to tie payments to overall quality performance.

Section 402(a)(1)(A), of the Social Security Amendments of 1967 (as amended), 42 U.S.C. 1395b–1(a)(1)(A) provided authority for CMS to conduct the Home Health Pay-for-Performance (HHPFP) Demonstration that ran from 2008 to 2010. The results of that Demonstration found limited quality improvement in certain measures after comparing the quality of care furnished by Demonstration participants to the quality of care furnished by the control group. One important lesson learned from the HHPFP Demonstration was the need to link the HHA's quality improvement efforts and the incentives. HHAs in three of the four regions generated enough savings to have incentive payments in the first year of the Demonstration, but the size of payments were unknown until after the conclusion of the Demonstration. This time lag on paying incentive payments did not provide a sufficient incentive to HHAs to make investments necessary to improve quality. The Demonstration suggested that future models could benefit from ensuring that incentives are reliable enough, of sufficient magnitude, and paid in a timely fashion to encourage HHAs to be fully engaged in the quality of care initiative. The evaluation report is available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/HHP4P_Demo_Eval_Final_Vol1.pdf.*

We have already successfully implemented the Hospital Value-Based Purchasing (HVBP) program where 1.25 percent of hospital payments in FY 2014 are tied to the quality of care that the hospitals provide. This percentage amount will gradually increase to 2.0 percent in FY 2017 and subsequent years. The President's 2015 Budget proposes that value-based purchasing should be extended to additional providers including skilled nursing facilities, home health agencies, ambulatory surgical centers, and hospital outpatient departments. Therefore, we are now considering testing a HHA VBP model that builds on what we have learned from the HVBP program. The model also presents an opportunity to test whether larger incentives than what have been previously tested will lead to even greater improvement in the quality of care furnished to beneficiaries. The HHA VBP model that is being considered will offer both a greater potential reward for high performing HHAs as well as a greater potential downside risk for low performing HHAs. If implemented, the model will begin at the outset of CY 2016, and include an array of measures that can capture the multiple dimensions of care that HHAs furnish. Building upon the successes of other related programs, we are seeking to implement a model with greater upside benefit and downside risk to motivate HHAs to make the substantive investments necessary to improve the quality of care furnished by HHAs.

As currently envisioned, the HHA VBP model would reduce or increase Medicare payments, in a 5–8 percent range, depending on the degree of quality performance in various measures to be selected. The model would apply to all HHAs in each of the projected five to eight states selected to participate in the model. The distribution of payments would be based on quality performance, as measured by both achievement and improvement across multiple quality measures. Some HHAs would receive higher payments than standard fee-for-service payments and some HHAs would receive lower payments, similar to the HVBP program. We believe the payment adjustment at risk would provide an incentive among all HHAs to provide significantly better quality through improved planning, coordination, and management of care. To be eligible for any incentive payments, HHAs would need to achieve a minimal threshold in quality performance with respect to the care that they furnish. The size of the award would be dependent on the level of quality furnished above the minimal threshold with the highest performance awards going to HHAs with the highest overall level of or improvement in quality.

HHAs that meet or exceed the performance standards based on quality and efficiency metrics would be eligible to earn performance payments. The size of the performance payment would be dependent upon the provider's performance relative to other HHAs within its participating state. HHAs that exceed the performance standards and demonstrate the greatest level of overall quality or quality improvement on the selected measures would have the opportunity to receive performance payment adjustments greater than the amount of the payment reduction, and would therefore see a net payment increase as a result of this model. Those HHAs that fail to meet the performance standard would receive lower payments than what would have been reimbursed under the traditional FFS Medicare payment system, and would therefore see a net payment decrease to Medicare payments as a result of this model. We stated in the proposed rule that we are proposing to use the waiver authority under section 1115A of the Act to waive the applicable Medicare payment provisions for HHAs in the selected states and apply a reduction or increase to current Medicare payments to these HHAs, which will be dependent on their performance.

We are considering a HHA VBP model in which participation by all HHAs in five to eight selected states is mandatory. We believe requiring all HHAs in selected states to participate in the model will ensure 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. In our experience, providers are generally reluctant to participate voluntarily in models in which their Medicare payments are subject to reduction. In the proposed rule, we invited comments on the HHA VBP model outlined above, including elements of the model, size of the payment incentives and percentage of payments that would need to be placed at risk in order to spur HHAs to make the necessary investments to improve the quality of care for Medicare beneficiaries, the timing of the incentive

payments, and how performance payments should be distributed. We also invited comments on the best approach for selecting states for participation in this model. Approaches could include: (1) Selecting states randomly, (2) selecting states based on quality, utilization, health IT, or efficiency metrics or a combination, or (3) other considerations. We noted that if we decide to move forward with the implementation of this HHA VBP model in CY 2016, we intended to invite additional comments on a more detailed model proposal to be included in future rulemaking.

We received a number of comments on the model design, including the following:

- A number of commenters expressed concern regarding the magnitude of 5–8 percent payment adjustment incentives, particularly when considering HHA margins, and as compared to the Hospital Value-based Purchasing program. A number of commenters also expressed support for a high payment incentive because they believe that this payment incentive will provide adequate remuneration for an investment in quality.
- A number of commenters encouraged a combination of pay-for-performance and pay-for-reporting .
- A number of commenters expressed ideas on the evaluation criteria under the model, for example: Not using the 5-star system, giving higher weight to quality measures relating to conditions requiring home health intervention, excluding HHCAHPS from the criteria due to timeliness reasons, excluding re-hospitalization metrics since they are often determined by physician judgment, and excluding OASIS measures since they might be fraudulently manipulated.
- A number of commenters expressed support for the inclusion of a beneficiary risk adjustment strategy to help prevent cherry picking of easier cases.
- A number of commenters preferred for HHAs to be allowed to select participation as opposed to the mandatory participation being considered by CMS.
- A number of commenters expressed opinions about the methodology for selecting the participating states, including choosing them from various MAC regions, choosing a rural and frontier state, and excluding states with moratoria on new HHAs.
- A number of commenters supported the development of a VBP model.

We thank all commenters for their input and will consider these comments as we make further decisions about implementing a HHA VBP model in CY 2016 which would assess performance from each of the preceding baseline years. As stated in the proposed rule, we intend to invite additional comments on a more detailed model proposal to be included in future rulemaking, including the selection of states and the criteria used for selection, the specific measures to be employed, how these measures are categorized within domains and the criteria used for selection, and the payment adjustment percentage.

J. Advancing Health Information Exchange

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'') The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies, (2) adoption of common standards and certification requirements for interoperable health IT, (3) support for privacy and security of patient information across all HIE-focused initiatives, and (4) governance of health information networks. These initiatives are designed to encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive programs, and are designed to improve care delivery and coordination across the entire care continuum. We believe that HIE and the use of certified EHR technology by HHAs (and other providers ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs).

Comments: Responses from commenters generally supported the use of EHRs to advance standards-based interoperable health information exchange, ensure privacy and security protections, and improve patient-centered quality care. Commenters noted the ability for health IT to enable access to essential information for decision-making by individuals, providers and their family caregivers. One commenter noted the possibility that some vendors may sunset products or increase costs as health IT standards are adopted. Other commenters noted the need for standards that recognize the distinct functional needs of the home care sector and requested notice regarding emerging standards to allow sufficient time for vendor and provider integration. Other commenters expressed concern regarding increased costs associated with implementing HIE and the lack of incentives to support capital expenditures.

Response: We thank commenters for their responses. HHS will continue to promote the adoption and implementation of certified health IT. The use of certified health IT can improve interoperability through the use of national, consensus-based standards as well as facilitate the secure interoperable exchange of health information. To increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472–73) an intent to propose future changes to the ONC HIT Certification Program that would permit the certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings. For now, we direct stakeholders to the ONC guidance for EHR technology developers serving providers ineligible for the Medicare and Medicaid EHR Incentive Programs titled ''Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments.'' [44] We encourage stakeholders to also review the Health IT Policy Committee (a Federal Advisory Committee) recommendations for areas in which certification under the ONC HIT Certification Program would help support long-term and post-acute care providers.[45] Further,

[44] *http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf. More information on the current development of standards applicable to HH can be found at: http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG and http://wiki.siframework.org/Longitudinal+Coordination+of+Care.*

[45] *http://www.healthit.gov/facas/sites/faca/files/TransmittalLetter_LTPAC_BH_Certification.pdf;*

stakeholders should consider emerging innovative payment models, quality reporting programs, state Medicaid reimbursement for remote monitoring (available in some states) and grants that could provide funding for health IT implementation for home health or incentivize other providers to assist home health providers' implementation efforts. For an overview of these opportunities, stakeholders are directed to the Health IT in Long-Term Post-Acute Care Issue Brief.[46]

K. Proposed Revisions to the Speech-Language Pathologist Personnel Qualifications

We proposed to revise the personnel qualifications for speech-language pathologists (SLP) to more closely align the regulatory requirements with those set forth in section 1861(ll) of the Act. We proposed to require that a qualified SLP be an individual who has a master's or doctoral degree in speech-language pathology, and who is licensed as a speech-language pathologist by the state in which he or she furnishes such services. To the extent of our knowledge, all states license SLPs; therefore, all SLPs would be covered by this option. We believe that deferring to the states to establish specific SLP requirements would allow all appropriate SLPs to provide services to Medicare beneficiaries. Should a state choose not to offer licensure at some point in the future, we proposed a second, more specific, option for qualification. In that circumstance, we proposed to require that a SLP successfully complete 350 clock hours of supervised clinical practicum (or be in the process of accumulating such supervised clinical experience); perform not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and successfully complete a national examination in speech-language pathology approved by the Secretary. These specific requirements are set forth in the Act, and we believe that they are appropriate for inclusion in the regulations as well.

We invited comments on this technical correction and associated change in the regulations at § 484.4 in section VI. We received five public comments regarding this proposal from individual HHAs, state HHA provider organizations, and a national organization representing SLPs.

Comment: All comments supported the deferral to state licensure standards and validated CMS' understanding that all states currently have licensure standards for SLPs. One commenter supported the inclusion of separate qualifications for those SLPs located in areas without state licensure, noting that these regulations would also apply in US Territories, and that not all Territories have licensure standards for SLPs.

Response: We agree with the commenters that the changes would be appropriate, and are finalizing them as such.

Comment: A commenter suggested that we should replace the specific education, training, and experience requirements set forth in the Social Security Act with a requirement that an SLP must meet the certification standards established by the American Speech-Language-Hearing Association (ASHA).

Response: The Social Security Act (the Act), on which the regulation is based, does not limit SLPs to only those individuals who meet the ASHA certification standards. Since this limitation does not exist in the Act, we do not believe it should exist in the regulations. Therefore, in order to align the regulatory requirements with those requirements set forth in the Act, we are not making the suggested change. States are free to require ASHA certification as part of their SLP licensure standards.

Comment: One comment sought clarification on why this change was being proposed at this time rather than as part of a comprehensive revision of the home health agency Conditions of Participation (CoPs).

Response: While a comprehensive revision of the home health CoPs is underway, we have received information from those in the SLP community that the restrictions currently in place for SLPs are impeding the ability of SLPs to practice. Finalizing a comprehensive revision to the home health agency CoPs will require several years. We believe that it is in the interest of the HHA and SLP communities, as well as the Medicare program, to effect a more timely change to the SLP personnel qualifications. Therefore, we are finalizing the revised requirements, as proposed, in this rule, and the change will be effective on January 1, 2015.

Final decision: We are finalizing the proposal without change.

L. Technical Regulations Text Changes

We proposed to make technical corrections in § 424.22(b)(1) to better align the recertification requirements with the Medicare Conditions of Participation (CoPs) for home health services. Specifically, we proposed that § 424.22(b)(1) will specify that recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode to coincide with the CoP requirements in § 484.55(d)(1), which require the HHA to update the comprehensive assessment in the last 5 days of every 60-day episode of care. As stated in § 484.55, the comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. We also proposed to specify in § 424.22(b)(1) that recertification is required at least every 60 days unless there is a beneficiary elected transfer or a discharge with goals met and return to the same HHA during the 60-day episode. The word ''unless'' was inadvertently left out of the payment regulations text. Inserting ''unless'' into § 424.22(b)(1) realigns the recertification requirements with the CoPs at § 484.55(d)(1).

As outlined in the ''Medicare Program; Prospective Payment System for Home Health Agencies'' final rule published on July 3, 2000 (65 FR 41188 through 41190), a partial episode payment (PEP) adjustment applies to two intervening events: (1) Where the beneficiary elects a transfer to another HHA during a 60-day episode or the patient; or (2) a discharge and return to the same HHA during the 60-day episode when a beneficiary reached the treatment goals in the plan of care. To discharge with goals met, the plan of care must be terminated with no anticipated need for additional home health services for the balance of the 60-day period. A PEP adjustment proportionally adjusts the national, standardized 60-day episode payment amount to reflect the length of time the beneficiary remained under the agency's care before the intervening event.

We proposed to revised § 424.22(b)(1)(ii) to clarify that if a beneficiary is discharged with goals met and/or no expectation of a return to home health care and returns to the same HHA during the 60-day episode a new start of care would be initiated (rather than an update to the comprehensive assessment) and thus the second episode will be considered a

http://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.

[46] *http://www.healthit.gov/sites/default/files/pdf/HIT_LTPAC_IssueBrief031513.pdf.*

certification, not a recertification,[47] and would be subject to § 424.22(a)(1).

We also proposed to make a technical correction in § 484.250(a)(1) to remove the ''-C'' after ''OASIS'' in § 484.250(a)(1), so that the regulation refers generically to the version of OASIS currently approved by the Secretary, and to align this section with the payment regulations at § 484.210(e). Specifically, an HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) for CMS to administer the payment rate methodologies described in § 484.215, § 484.230, and § 484.235 and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

Most of the comments that we received, where the commenter indicated that they were commenting on these technical corrections and associated changes in the regulations at § 424.22 and § 484.250 in section VI, were, in fact, also commenting on the proposed clarification on when documentation of a face-to-face encounter is required in section III.B.3. While we are finalizing these regulations text changes as proposed, we refer readers to the summary of the comments and responses in section III.B.3. for our rationale.

Final Decision: We are finalizing the proposed regulations text changed at § 424.22 and § 484.250 as proposed.

M. Survey and Enforcement Requirements for Home Health Agencies

1. Statutory Background and Authority

Section 4023 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L 100–203, enacted on December 22, 1987) added subsections 1891(e) and (f) to the Act, which expanded the Secretary's options to enforce federal requirements for home health agencies (HHAs or the agency). Sections 1861(e)(1) and (2) of the Act provide that if CMS determines that an HHA is not in compliance with the Medicare home health Conditions of Participation and the deficiencies involved either do, or do not, immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, then we may terminate the provider agreement, impose an alternative sanction(s), or both. Section 1891(f)(1)(B) of the Act authorizes the Secretary to develop and implement appropriate procedures for appealing determinations relating to the imposition of alternative sanctions.

In the November 8, 2012 **Federal Register** (77 FR 67068), we published the ''Alternative Sanctions for Home Health Agencies With Deficiencies'' final rule (part 488, subpart J), as well as made corresponding revisions to sections § 489.53 and § 498.3. This subpart J added the rules for enforcement actions for HHAs including alternative sanctions. Section 488.810(g) provides that 42 CFR part 498 applies when an HHA requests a hearing on a determination of noncompliance that leads to the imposition of a sanction, including termination. Section 488.845(b) describes the ranges of CMPs that may be imposed for all condition-level findings: upper range ($8,500 to $10,000); middle range ($1,500 to $8,500); lower range ($500 to $4,000), as well as CMPs imposed per instance of noncompliance ($1,000 to $10,000).

Section 488.845(c)(2) addresses the appeals procedures when CMPs are imposed, including the need for any appeal request to meet the requirements of § 498.40 and the option for waiver of a hearing.

2. Reviewability Pursuant to Appeals

We proposed to amend § 488.845 by adding a new paragraph (h) which would explain the reviewability of a CMP that is imposed on a HHA for noncompliance with federal participation requirements. The new language will provide that when administrative law judges (ALJs), state hearing officers (or higher administrative review authorities) find that the basis for imposing a civil money penalty exists, as specified in § 488.485, he or she may not set a penalty of zero or reduce a penalty to zero; review the exercise of discretion by CMS or the state to impose a civil money penalty; or, in reviewing the amount of the penalty, consider any factors other than those specified in §§ 488.485(b)(1)(i) through (b)(1)(iv). That is, when the administrative law judge or state hearing officer (or higher administrative review authority) finds noncompliance supporting the imposition of the CMP, he or she must retain some amount of penalty consistent with the ranges of penalty amounts established in § 488.845(b). The proposed language for HHA reviews is similar to the current § 488.438(e) governing the scope of review for civil money penalties imposed against skilled nursing facilities, and is also consistent with section 1128A(d) of the Act which requires that specific factors be considered in determining the amount of any penalty.

The following is a summary of the comments we received regarding the proposed amendment to § 488.845 to explain the reviewability of a CMP by an ALJ.

Comment: One commenter supported the proposal, as it would align HHA policy more closely with SNF policy regarding ALJ reviewability.

Response: We agree with the commenter who observed that the proposal would align HHA policy with long-standing practice and policy with regard to the manner in which SNF CMPs are reviewed. We believe it is important that CMS be consistent in the application of CMPs among providers, and the proposed language for HHA CMPs is consistent with existing language for SNFs at § 488.438(e).

Comment: Two commenters believed that the HHA CMP process was too new for changes to be addressed in the ALJ review process.

Response: The length of time the HHA CMPs have been in effect is not relevant to the implementation of the requirements of the Act and implementing regulations. Section 1891(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of a sanction. As provided at § 488.845(c)(2)(i) ''Appeals Procedures'', the determination that is the basis for imposition of the CMP may be appealed. The proposed language does not revise the regulation at § 488.845(c)(2)(i), but adds clarification regarding the scope of the review during the appeal process.

Comment: One commenter believed that the ALJs should be allowed to eliminate CMPs as a part of their administrative review.

Response: Section 1891(b) of the Act mandates that it is the duty and responsibility of the Secretary to assure that the conditions of participation as well as the enforcement of such conditions is adequate to protect the health and safety of individuals under the care of an HHA. Section 1891(f) of the Act further specifies that the Secretary establish a range of intermediate sanctions which shall include, among others, civil money penalties. Finally, section 1819(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of the sanction and the implementing regulations at § 488.845(c)(2)(i), ''Appeals Procedures'' provide that the determination that is the basis for imposition of the CMP may be appealed. It is within our discretion as to the choice of remedy to be imposed. While an ALJ may review the underlying findings that support CMS's determination to impose a CMP and

[47] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/downloads/OASISConsiderationsforPPS.pdf*

whether or not the imposed amount falls within the regulatory range, elimination of any CMP is not within the scope of the appeal process.

Comment: One commenter believed the denial of appeal of the implementation of the CMP may not be constitutionally valid. An additional two commenters believed this proposed language added additional restrictions to the ALJ which resulted in the lack of due process.

Response: We do not believe that the proposed language raises constitutional issues or restricts due process. Section 1128A of the Act requires that specific factors be considered in determining the amount of the penalty. Those factors, particularly the deficiencies cited by the survey, are considered by CMS in the establishment of the CMP amount to be imposed. The deficiencies which give rise to a CMP may be appealed. Section 1891(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of the sanction. These procedures are provided at § 488.845(c)(2)(i). The CMP itself would be affected if the deficiencies underlying the determination were not sustained on appeal.

Final Decision: After careful consideration of the comments received, we are finalizing the regulatory language as proposed.

3. Technical Adjustment

We also proposed to amend § 498.3, Scope and Applicability, by revising paragraph (b)(13) to include specific cross reference to proposed § 488.845(h) and to revise the reference to section § 488.740 which was a typographical error and replace it with section § 488.820 which is the actual section that lists the sanctions available to be imposed against an HHA. We also amended § 498.3(b)(14)(i) to include cross reference to proposed § 488.845(h), which establishes the scope of CMP review for HHAs. Finally, we proposed to amend § 498.60 to include specific references to HHAs and proposed § 488.845(h).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, 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 Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on the information collection requirement (ICR) related to the proposed changes to the home health face-to-face encounter requirements in section III.B and the proposed change to the therapy reassessment timeframes in section III.H. These proposed changes are associated with ICR approved under OMB control number as 0938–1083.

A. Proposed Changes to the Face-to-Face Encounter Requirements

The following assumptions were used in estimating the burden for the proposed changes to the home health face-to-face requirements:

TABLE 37—HOME HEALTH FACE-TO-FACE ENCOUNTER BURDEN ESTIMATE ASSUMPTIONS

# of Medicare-billing HHAs, from CY 2013 claims with matched OASIS assessments	11,521
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43–6014)	$20.54 ($15.80 ×; 1.30)
Hourly rate of an administrator (General and Operations Managers, 11–1021)	$64.65 ($49.73 ×; 1.30)
Hourly rate of Family and General Practitioners (29–1062)	$112.91 ($86.85 ×; 1.30)

Note: CY = Calendar Year.

All salary information is from the Bureau of Labor Statistics (BLS) Web site at *http://www.bls.gov/oes/current/naics4_621600.htm* and includes a fringe benefits package worth 30 percent of the base salary. The mean hourly wage rates are based on May 2013 BLS data for each discipline, for those providing ''home health care services.''

1. Proposed Changes to the Face-to-Face Encounter Narrative Requirement

Sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, as amended by section 6407 of the Affordable Care Act require that, as a condition for payment, prior to certifying a patient's eligibility for the Medicare home health benefit the physician must document that the physician himself or herself or an allowed nonphysician practitioner (NPP) had a face-to-face encounter with the patient. Section 424.22(a)(1)(v) currently requires that that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days after the start of the home health care. In addition, as part of the certification of eligibly, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in section 1835(a) of the Act, and in need of either intermittent skilled nursing services or therapy services, as defined in § 409.42(c).

To simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, we propose to eliminate the narrative requirement at § 424.22(a)(1)(v). The certifying physician will still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility.

In eliminating the face-to-face encounter narrative requirement, we assume that there will be a one-time burden for the HHA to modify the certification form, which the HHA provides to the certifying physician. The revised certification form must allow the certifying physician to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care

and was performed by a physician or allowed NPP as defined in § 424.22(a)(1)(v)(A). In addition, the certification form must allow the certifying physician to document the date that the face-to-face encounter occurred.

We estimate that it would take a home health clerical staff person 15 minutes (15/60 = 0.25 hours) to modify the certification form, and the HHA administrator 15 minutes (15/60 = 0.25 hours) to review the revised form. The clerical time plus administrator time equals a one-time burden of 30 minutes or (30/60) = 0.50 hours per HHA. For all 11,521 HHAs, the total time required would be (0.50 ×; 11,521) = 5,761 hours. At $20.54 per hour for an office employee, the cost per HHA would be (0.25 ×; $20.54) = $5.14. At $64.65 per hour for the administrator's time, the cost per HHA would be (0.25 × $64.65) = $16.16. Therefore, the total one-time cost per HHA would be $21.30, and the total one-time cost for all HHAs would be ($21.30 × 11,521) = $245,397.

In the CY 2011 HH PPS final rule (75 FR 70455), we estimated that the certifying physician's burden for composing the face-to-face encounter narrative, which includes how the clinical findings of the encounter support eligibility (writing, typing, or dictating the face-to-face encounter narrative) signing, and dating the patient's face-to-face encounter, was 5 minutes for each certification (5/60 = 0.0833 hours). Because it has been our longstanding manual policy that physicians sign and date certifications and recertifications, there is no additional burden to physicians for signing and dating the face-to-face encounter documentation. We estimate that there would be 3,096,680 initial home health episodes in a year based on 2012 claims data from the home health Datalink file. As such, the estimated burden for the certifying physician to write the face-to-face encounter narrative would have been 0.0833 hours per certification (5/60 = 0.0833 hours) or 257,953 hours total (0.0833 hours × 3,096,680 initial home health episodes). The estimated cost for the certifying physician to write to face-to-face encounter narrative would have been $9.41 per certification (0.0833 × $112.91) or $29,139,759 total ($9.41 × 3,096,680) for CY 2015.

Although we proposed to eliminate the narrative, the certifying physician will still be required to document the date of the face-to-face encounter as part of the certification of eligibility. We estimate that it would take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1/60 = 0.0166 hours). The estimated burden for the certifying physician to continue to document the date of the face-to-face encounter would be 0.0166 hours per certification or 51,405 hours total (0.0166 hours × 3,096,680 initial home health episodes). The estimated cost for the certifying physician to continue to document the date of the face-to-face encounter would be $1.87 per certification (0.0166 × $112.91) or $5,790,792 total ($1.87 × 3,096,680) for CY 2015. Therefore, in eliminating the face-to-face encounter narrative requirement, as proposed in section III.B. of the proposed rule, we estimate that burden and costs will be reduced for certifying physicians by 206,548 hours (257,953–51,405) and $23,348,967 ($29,139,759–$5,790,792), respectively for CY 2015.

Comment: A commenter believed that the time estimates were under-reported for the HHA administrator (15 minutes (15/60 = 0.25 hours)) to review the revised certification form. The commenter stated that the administrator would have to review the pertinent statutory and regulatory references to ensure that the certification form is in compliance.

Response: Since all certification requirements are remaining the same, except for the elimination of the narrative, the administrator should already be knowledgeable about the current statutory and regulatory requirements with regard to certifying patient eligibility for the home health benefit. Therefore, we will maintain our original estimate that it will take no more than 15 minutes for the HHA administrator to review the necessary changes to the certification form as a result of the elimination of the face-to-face encounter narrative.

2. Proposed Clarification on When Documentation of a Face-to-Face Encounter Is Required

To determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, we proposed to clarify that the face-to-face encounter requirement is applicable for certifications (not recertifications), rather than initial episodes. A certification (versus recertification) is generally considered to be any time that a new SOC OASIS is completed to initiate care. We estimate that of the 6,562,856 episodes in the CY 2012 home health Datalink file, 3,096,680 SOC assessments were performed on initial home health episodes. If this proposal is implemented, an additional 830,287 episodes would require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new SOC OASIS assessment. We estimate that it would take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1/60 = 0.0166 hours). The estimated burden for the certifying physician to document the date of the face-to-face encounter for each certification (any time a new SOC OASIS is completed to initiate care) would be 0.0166 hours or 13,783 total hours (0.0166 hours × 830,287 additional home health episodes). The estimated cost for the certifying physician to document the date of the face-to-face encounter for each additional home health episode would be $1.87 per certification (0.0166 × $112.91) or $1,552,637 total ($1.87 × 830,287) for CY 2015.

TABLE 38—ESTIMATED ONE-TIME FORM REVISION BURDEN FOR HHAS

OMB#	Requirement	HHAs	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	11,521	1	0.5	5,761	$245,397

TABLE 39—ESTIMATED BURDEN REDUCTION FOR CERTIFYING PHYSICIANS

[No longer drafting a face-to-face encounter narrative]

OMB#	Requirement	Certifications	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	3,096,680	1	(0.0667)	(206,548)	($23,348,967)

TABLE 40—ESTIMATED BURDEN FOR CERTIFYING PHYSICIANS

[Documenting the date of the face-to-face encounter for additional certifications]

OMB#	Requirement	Certifications	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	830,287	1	0.0166	13,783	$1,552,637

In summary, all of the changes to the face-to-face encounter requirements in section III.B of this final rule, including changes to § 424.22(a)(1)(v), will result in an estimated net reduction in burden for certifying physicians of 192,765 hours or $21,796,330 (see Tables 39 and 40). The changes to the face-to-face encounter requirements at § 424.22(a)(1)(v) will result in a one-time burden for HHAs to revise the certification form of 5,761 hours or $245,397 (Table 38 above).

B. Proposed Change to the Therapy Reassessment Timeframes

Currently, § 409.44(c) requires that patient's function must be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method which would include objective measurement. If more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must perform the assessment and periodic reassessments. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record. At least every 30 days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. If a patient is expected to require 13 and/or 19 therapy visits, a qualified therapist (instead of an assistant) must provide all of the therapy services on the 13th visit and/or 19th therapy visit and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). When the patient resides in a rural area or if the patient is receiving multiple types of therapy, a therapist from each discipline (not an assistant) must assess the patient after the 10th therapy visit but no later than the 13th therapy visit and after the 16th therapy visit but no later than the 19th therapy visit for the plan of care. In instances where the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra unnecessary visit or delaying a visit, then it is acceptable for the qualified therapist from that discipline to provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 14th and/or 20th Medicare-covered therapy visit, but no later than the 13th and/or 19th Medicare-covered therapy visit. When a therapy reassessment is missed, any visits for that discipline prior to the next reassessment are non-covered.

To lessen the burden on HHAs of counting visits and to reduce the risk of non-covered visits so that therapists can focus more on providing quality care for their patients, we are simplifying § 409.44(c) to require that therapy reassessments must be performed at least once every 30 calendar days. The requirement to perform a therapy reassessment at least once every 30 calendar days would apply to all episodes regardless of the number of therapy visits provided. All other requirements related to therapy reassessments would remain unchanged. A qualified therapist (instead of an assistant), from each therapy discipline provided, must provide the ordered therapy service and functionally reassess the patient using a method which would include objective measurement. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record.

In the CY 2011 HH PPS final rule we stated that the therapy reassessment requirements in § 409.44(c) are already part of the home health CoPs, as well as from accepted standards of clinical practice, and therefore, we believe that these requirements do not create any additional burden on HHAs (75 FR 70454). As stated in the CY 2011 HH PPS final rule, longstanding CoP policy at § 484.55 requires HHAs to document progress toward goals and the regulations at § 409.44(c)(2)(i) already mandate that for therapy services to be covered in the home health setting, the services must be considered under accepted practice to be a specific, safe, and effective treatment for the beneficiary's condition. The functional assessment does not require a special visit to the patient, but is conducted as part of a regularly scheduled therapy visit. Functional assessments are necessary to demonstrate progress (or the lack thereof) toward therapy goals, and are already part of accepted standards of clinical practice, which include assessing a patient's function on an ongoing basis as part of each visit. The CY 2011 HH PPS final rule goes on to state that both the functional assessment and its accompanying documentation are already part of existing HHA practices and accepted standards of clinical practice. Therefore, we continue to believe that simplifying the required reassessment timeframes from every 30 days and prior to the 14th and 20th visits to every 30 calendar days does not place any new documentation requirements on HHAs.

We are revising the currently approved PRA package (OMB# 0938–1083) to describe these changes to the regulatory text.

C. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule.

PRA-specific comments must be received on/by December 8, 2014.

V. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for 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, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(5) of the Act gives the Secretary 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. Also, section 1886(d)(2)(D) of the Act requires that home health services furnished in a rural area for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent the payment amount otherwise made under section 1895 of the Act.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as economically significant under section 3(f)(1) of Executive Order 12866, since the aggregate transfer impacts in calendar year 2015 will exceed the $100 million threshold. The net transfer impacts are estimated to be −$60 million. Furthermore, we estimate a net reduction of $21.55 million in calendar year 2015 burden costs related to the certification requirements for home health agencies and associated physicians. Lastly, this final rule is a major rule under the Congressional Review Act and as a result, we have prepared a regulatory impact analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2015. Accordingly, the following analysis describes the impact in CY 2015 only. We estimate that the net impact of the proposals in this rule is approximately $60 million in decreased payments to HHAs in CY 2015. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.D.4. of this final rule; therefore, the estimated impact of the 2015 wage index in section III.D.3. of this final rule and the recalibration of the case-mix weights for 2015 in section III.C. of this final rule is zero. The −$60 million impact reflects the distributional effects of the 2.1 percent home health payment update percentage ($390 million increase) and the effects of the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit payment rates, and the NRS conversion factor for an impact of −2.4 percent ($450 million decrease). The $60 million in decreased payments is reflected in the last column of the first row in Table 41 as a 0.3 percent decrease in expenditures when comparing estimated CY 2014 payments to estimated CY 2015 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 consider all HHAs 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 for this final rule, which incorporates additional Medicare home health claims data that were not available at the time the CY 2015 HH PPS proposed rule was published, we conclude that the policies final in this 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 final rule will have a significant economic impact on a substantial number of small entities. Further detailed analysis is presented below and in Table 41, by HHA classification, type, and location.

Executive Order 13563 specifies, to the extent practicable, agencies should assess the costs of cumulative regulations. However, given potential utilization pattern changes, wage index changes, changes to the market basket forecasts, and unknowns regarding future policy changes, we believe it is neither practicable nor appropriate to forecast the cumulative impact of the rebasing adjustments on Medicare payments to HHAs for future years at this time. Changes to the Medicare program may continue to be made as a result of the Affordable Care Act or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact and the complexity of the interactions would make it difficult to predict accurately the full scope of the impact upon HHAs for future years beyond CY 2015. We note that the rebasing adjustments to the national, standardized 60-day episode payment rate and the national per-visit rates are capped at the statutory limit of 3.5 percent of the CY 2010 amounts for each year, 2014 through 2017, and the NRS rebasing adjustment will be −2.82 percent in each year, 2014 through 2017 (as described in section II.C. of this final rule).

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule applies to HHAs. Therefore, the Secretary has determined that this rule will not have a significant economic impact on the operations of small rural hospitals.

C. Detailed Economic Analysis

This final rule sets forth updates for CY 2015 to the HH PPS rates contained in the CY 2014 HH PPS final rule (78 FR 72304 through 72308). The impact analysis of this final rule presents the estimated expenditure effects of policy changes final in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, primarily using Medicare claims data for CY 2013. 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 interactions could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 41 represents how HHA revenues are likely to be affected by the policy changes finalized in this rule. For this analysis, we used an analytic file of CY 2013 home health claims data (as of June 30, 2014) for dates of service that ended on or before December 31, 2013, linked to OASIS assessments. The first column of Table 41 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The third column shows the payment effects of CY 2015 wage index. The fourth column shows the payment effects of the CY 2015 case-mix weights. The fifth column shows the effects of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and NRS conversion factor. The sixth column shows the effects of the CY 2015 home health payment update percentage (the home health market basket update adjusted for multifactor productivity as discussed in section III.D.1. of this final rule). The last column shows the overall payment effects of all the policies discussed in this final rule.

As illustrated in Table 41, the combined effects of all of the changes vary by specific types of providers and by location. A substantial amount of the variation in the estimated impacts of the policies finalized in this rule in different areas of the country can be attributed to variations in the CY 2015 wage index used to adjust payments under the HH PPS and to the effects of the recalibration of the HH PPS case-mix weights. For example, the estimated impact due to the recalibration of the HH PPS case-mix weights for the West South Central census region is a 2.2 percent decrease in payments for CY 2015. The case-mix weights for third or later episodes of care with no or low therapy generally decreased as a result of the recalibration of the HH PPS case-mix weights (see section III.C. of this final rule). In the West South Central region, approximately one-third of episodes are either the first or second episode of care and nearly two-thirds of episodes are the third or later episode of care (analysis of episodes with 0–19 therapy visits). This differs drastically from the rest of the nation where over two-thirds of episodes are either the first or second episode of care and less than one-third of episodes are the third or later episode of care (analysis of episodes with 0–19 therapy visits). Thus, the West South Central census region experiences a larger estimated reduction in payments due to the recalibration of the case-mix weights because it has a much larger share of episodes that are the third or later episode compared to the rest of the nation. Instances where the impact, due to the rebasing adjustments, is less than others can be attributed to differences in the incidence of outlier payments and LUPA episodes, which are paid using the national per-visit payment rates that are subject to payment increases due to the rebasing adjustments. 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 2015 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2015 relative to CY 2014, and the degree of Medicare utilization.

For CY 2015, the average impact for all HHAs due to the effects of rebasing is an estimated 2.4 percent decrease in payments. The overall impact for all HHAs as a result of this final rule is a decrease of approximately 0.3 percent in estimated total payments from CY 2014 to CY 2015.

TABLE 41—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2015

	Number of agencies	CY 2015 wage index [1] (percentage)	CY 2015 case-mix weights [2] (percentage)	Rebasing [3] (percentage)	CY 2015 HH payment update percentage [4]	Impact of all CY 2015 policies (percentage)
All Agencies	11,781	0.0	0.0	−2.4	2.1	−0.3
Facility Type and Control:						
Free-Standing/Other Vol/NP	1,062	0.3	1.0	−2.3	2.1	1.1
Free-Standing/Other Proprietary	9,194	−0.1	−0.5	−2.4	2.1	−0.9
Free-Standing/Other Government	402	0.4	0.5	−2.3	2.1	0.7
Facility-Based Vol/NP	774	0.2	1.6	−2.3	2.1	1.6
Facility-Based Proprietary	115	−0.2	1.3	−2.3	2.1	0.9
Facility-Based Government	234	0.2	1.4	−2.4	2.1	1.3
Subtotal: Freestanding	10,658	0.0	−0.2	−2.4	2.1	−0.5
Subtotal: Facility-based	1,123	0.2	1.5	−2.3	2.1	1.5
Subtotal: Vol/NP	1,836	0.3	1.2	−2.3	2.1	1.3
Subtotal: Proprietary	9,309	−0.1	−0.5	−2.4	2.1	−0.9
Subtotal: Government	636	0.3	0.9	−2.3	2.1	1.0
Facility Type and Control: Rural:						
Free-Standing/Other Vol/NP	192	0.1	1.3	−2.3	2.1	1.2
Free-Standing/Other Proprietary	140	0.9	0.6	−2.4	2.1	1.2
Free-Standing/Other Government	466	0.2	−0.6	−2.4	2.1	−0.7
Facility-Based Vol/NP	251	0.6	1.5	−2.5	2.1	1.8
Facility-Based Proprietary	27	0.1	0.3	−2.5	2.1	0.0
Facility-Based Government	137	0.6	1.3	−2.3	2.1	1.7
Facility Type and Control: Urban:						
Free-Standing/Other Vol/NP	922	0.3	1.0	−2.3	2.1	1.1
Free-Standing/Other Proprietary	8,870	−0.1	−0.5	−2.4	2.1	−0.9
Free-Standing/Other Government	164	0.3	0.5	−2.4	2.1	0.5
Facility-Based Vol/NP	523	0.2	1.6	−2.3	2.1	1.6
Facility-Based Proprietary	88	−0.2	1.4	−2.3	2.1	1.0
Facility-Based Government	97	0.0	1.4	−2.4	2.1	1.1
Facility Location: Urban or Rural:						
Rural	1,117	0.4	0.4	−2.4	2.1	0.5
Urban	10,664	0.0	0.0	−2.4	2.1	−0.3
Facility Location: Region of the Country:						
Northeast	882	0.4	0.9	−2.2	2.1	1.2
Midwest	3,165	0.2	0.8	−2.5	2.1	0.6
South	5,722	−0.3	−0.9	−2.4	2.1	−1.5
West	1,962	0.5	0.9	−2.4	2.1	1.1
Other	50	1.7	1.8	−2.4	2.1	3.2
Facility Location: Region of the Country (Census Region):						
New England	340	0.8	0.9	−2.2	2.1	1.6
Mid Atlantic	542	0.1	0.9	−2.1	2.1	1.0
East North Central	2,415	0.2	0.6	−2.5	2.1	0.4
West North Central	750	0.1	1.6	−2.4	2.1	1.4
South Atlantic	2,054	−0.1	0.0	−2.4	2.1	−0.4
East South Central	440	−0.6	0.0	−2.5	2.1	−1.0
West South Central	3,228	−0.5	−2.2	−2.4	2.1	−3.0
Mountain	689	0.4	1.5	−2.4	2.1	1.6
Pacific	1,273	0.5	0.6	−2.4	2.1	0.8
Facility Size (Number of 1st Episodes):						
< 100 episodes	2,924	−0.3	−0.3	−2.4	2.1	−0.9
100 to 249	2,767	−0.3	−0.6	−2.4	2.1	−1.2
250 to 499	2,569	−0.2	−0.8	−2.4	2.1	−1.3
500 to 999	1,878	0.0	−0.2	−2.4	2.1	−0.5
1,000 or More	1,643	0.1	0.3	−2.4	2.1	0.1

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment.

[1] The impact of the CY 2015 home health wage index reflects the transition to new CBSA designations as outlined in section III.D.3 this final rule offset by the wage index budget neutrality factor described in section III.D.4 this final rule.

[2] The impact of the CY 2015 home health case-mix weights reflects the recalibration of the case-mix weights as outlined in section III.C of this final rule offset by the case-mix weight budget neutrality factor described in section III.D.4 of this final rule.

[3] The impact of rebasing includes the rebasing adjustments to the national, standardized 60-day episode payment rate (−2.73 percent after the CY 2014 payment rate was adjusted for the wage index and case-mix weight budget neutrality factors), the national per-visit rates (+3.26 percent), and the NRS conversion factor (−2.82%). The estimated impact of the NRS conversion factor rebasing adjustment is an overall −0.01 percent decrease in estimated payments to HHAs. The overall impact of all the rebasing adjustments finalized in the CY 2014 HH PPS proposed rule and implemented for CY 2015 are lower than the overall impact in the CY 2014 due to the case-mix budget neutrality factor and an increase in estimated outlier payments. As the national per-visit rates increase and the national, standardized 60-day episode rate decreases more episodes qualify for outlier payments. In addition, we decreased the fixed-dollar loss (FDL) ratio from 0.67 to 0.45 effective CY 2013 in order to qualify more episodes as outliers, and we use CY 2013 utilization in simulating impacts for the CY 2015 HH PPS final rule.

[4] The CY 2015 home health payment update percentage reflects the home health market basket update of 2.6 percent, reduced by a 0.5 percentage point multifactor productivity (MFP) adjustment as required under section 1895(b)(3)(B)(vi)(I) of the Act, as described in section III.D.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; **Outlying** = Guam, Puerto Rico, Virgin Islands.

D. Anticipated Effects

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 one year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule is not anticipated to have an effect on state, local, or tribal governments in the aggregate, or by the private sector, of $141 million or more in CY 2015.

E. Alternatives Considered

In recalibrating the HH PPS case-mix weights for CY 2015, as discussed in section III.C. of this final rule, we considered adjusting the payment rates in section III.D.4 to make the recalibration budget neutral only with regard to our estimate of real case-mix growth between CY 2012 and the CY 2013. Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions for nominal case-mix growth—changes in case-mix that are unrelated to actual changes in patient health status. However, instead of implementing a case-mix budget neutrality factor that only reflects our estimate of real increases in patient severity; we finalized the recalibration of the case-mix weights in a fully budget-neutral manner. We will continue to monitor case-mix growth (both real and nominal case-mix growth) as more data become available.

With regard to the adoption of the revised OMB delineations for purposes of calculating the wage index, we will implement the new OMB delineations as we believe they will result in wage index values being more representative of the actual costs of labor in a given area. We considered having no transition period and fully implementing the new OMB delineations beginning in CY 2015. However, this would not provide time for HHAs to adapt to the new OMB delineations. We believe that a transition period would help to mitigate the potential for resulting short-term instability and negative impact on certain HHAs, and to provide time for HHAs to adjust to their new labor market area delineations. In determining an appropriate transition methodology, consistent with the objectives set forth in the FY 2006 SNF PPS final rule (70 FR 45041), we first considered transitioning the wage index to the revised OMB delineations over a number of years in order minimize the impact of the wage index changes in a given year. However, the transition must be balanced against the need to ensure the most accurate payments possible, which called for a faster transition to the revised OMB delineations. As such, utilizing a one-year (rather than a multiple year) transition with a blended wage index in CY 2015 will strike the best balance. Second, we considered what type of blend would be appropriate for purposes of the transition wage index. We are finalizing that HHAs will receive a one-year blended wage index using 50 percent of their CY 2015 wage index based on the new OMB delineations and 50 percent of their CY 2015 wage index based on the FY 2014 OMB delineations. A 50/50 blend best mitigates the negative payment impacts associated with the implementation of the new OMB delineations. While we considered alternatives to the 50/50 blend, this type of split balances the increases and decreases in wage index values as well as provides a readily understandable calculation for HHAs.

Next, we considered whether or not the blended wage index should be used for all HHAs or for only a subset of HHAs, such as those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations. As required in section 1895(b)(3) of the Act, the wage index adjustment must be implemented in a budget-neutral manner. If we were to apply the transition policy only to those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations, the wage index budget neutrality factor, discussed in section III.D.4, would result in reduced base rates for all HHAs as compared to the budget neutrality factor that results from applying the blended wage index to all HHAs.

For the reasons discussed above, we believe that finalizing our proposal to use a one-year transition with a 50/50 blended wage index in CY 2015 as this policy balances the interests of all HHAs and will best achieve our objective of providing relief to negatively impacted HHAs.

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

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2015 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2015, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket update under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Beginning in CY 2015, section 1895(b)(3)(B)(vi)(I) of the Act, as amended by section 3401(e) of the Affordable Care Act, requires the application of the productivity

adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HHA PPS for CY 2015 and each subsequent CY. The −0.5 percentage point productivity adjustment to the CY 2015 home health market basket update (2.6 percent) is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act (as amended by the Affordable Care Act).

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 42, we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this final rule. Table 42 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes finalized in this rule. Table 42 also reflects the estimated change in costs and burden for certifying physicians and HHAs as a result of the changes to the face-to-face encounter requirements finalized in section III.B. We estimate a net reduction in burden for certifying physicians of 192,765 hours or $21,796,330 (see section IV of this rule). In addition, Table 42 reflects our estimate of a one-time burden for HHAs to revise the certification form of 5,761 hours or $245,397 as described in section IV. of this rule.

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM THE CYS 2014 TO 2015 *

Category	Transfers
Annualized monetized transfers	−$60 million.
From Whom to Whom?	Federal Government to HHAs.
Category	**Costs**
Annualized Monetized Net Burden for Physicians Certifying Patient Eligibility for Home Health Services & HHAs for Certification Form Revision.	−$21.55 million.

* The estimates reflect 2014 dollars.

G. Conclusion

In conclusion, we estimate that the net impact of this final rule is a decrease in Medicare payments to HHAs of $60 million for CY 2015. The $60 million decrease in estimated payments for CY 2015 reflects the distributional effects of the 2.1 percent CY 2015 home health payment update percentage ($390 million increase) and the second year of the 4-year phase-in of the rebasing adjustments required by section 3131(a) of the Affordable Care Act ($450 million decrease). Also, starting in CY 2015, certifying physicians are estimated to incur a net reduction in burden costs of $21,796,330 and HHAs are expected to incur a one-time increase in burden costs to revise the certification form of $245,397 as a result of the elimination of the face-to-face encounter narrative requirement finalized in section III.B. This analysis, together with the remainder of this preamble, constitutes the Regulatory Flexibility Analysis.

VI. 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.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 498

Health facilities, Medicare, Reporting and recordkeeping requirements.

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

PART 409—HOSPITAL INSURANCE BENEFITS

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

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

§ 409.44 [Amended]

■ 2. Section 409.44 is amended by—
■ a. Removing ''intermediary's'' from paragraph (a) and adding ''Medicare Administrative Contractor's'' in its place.
■ b. Adding ''calendar'' between ''30'' and ''days'' in paragraph (c)(2)(i)(B).
■ c. Removing paragraphs (c)(2)(i)(C) and (D).
■ d. Redesignating paragraphs (c)(2)(i)(E) through (H) as paragraphs (c)(2)(i)(C) through (F).
■ e. Removing ''(c)(2)(i)(A), (B), (C), and (D) of this section,'' from newly redesignated paragraph (c)(2)(i)(C) introductory text and adding ''(c)(2)(i)(A) and (B) of this section,'' in its place.
■ f. Removing ''(c)(2)(i)(E)(*2*) and (c)(2)(i)(E)(*3*) of this section are met,'' from newly redesignated paragraph (c)(2)(i)(C)(*1*) and adding ''(c)(2)(i)(C)(*2*) and (c)(2)(i)(C)(*3*) of this section are met,'' in its place.
■ g. Removing ''§ 409.44(c)(2)(i)(H) of this section.'' from newly redesignated paragraph (c)(2)(i)(C)(*3*) and adding ''paragraph (c)(2)(i)(F) of this section.'' in its place.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 3. The authority citation for part 424 continues to read as follows:

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

■ 4. Section 424.22 is amended by—

■ a. Revising paragraphs (a) and (b) and adding new paragraph (c).
■ b. Removing ''(d)(i)'' from paragraph (d)(2) and adding ''(d)(1)'' in its place.

The revisions read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify the patient's eligibility for the home health benefit, as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as follows in paragraphs (a)(1)(i) through (v) of this section. The patient's medical record, as specified in paragraph (c) of this section, must support the certification of eligibility as outlined in paragraph (a)(1)(i) through (v) of this section.

(i) The individual needs or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services as defined in § 409.42(c) of this chapter. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services are or were required because the individual is or was confined to the home, as defined in sections 1835(a) and 1814(a) of the Act, except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and will be or was periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services will be or were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(v) A face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in paragraph (a)(1)(v)(A) of this section. The certifying physician must also document the date of the encounter as part of the certification.

(A) The face-to-face encounter must be performed by one of the following:

(*1*) The certifying physician himself or herself.

(*2*) A physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health.

(*3*) A nurse practitioner or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in accordance with State law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*4*) A certified nurse midwife (as defined in section 1861(gg) of the Act) as authorized by State law, under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*5*) A physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(B) The face-to-face patient encounter may occur through telehealth, in compliance with section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

(*1*) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(*2*) [Reserved]

(2) [Reserved]

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed, and must be signed and dated by the physician who reviews the plan of care. Recertification is required at least every 60 days unless there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge with goals met and/or no expectation of a return to home health care.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* Documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) shall be used as the basis for certification of home health eligibility. This documentation shall be provided upon request to the home health agency, review entities, and/or CMS. Criteria for patient eligibility are described in paragraphs (a)(1) and (b) of this section. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

* * * * *

PART 484—HOME HEALTH SERVICES

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

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

■ 6. Section 484.4 is amended by revising the definition of ''Speech-language pathologist'' to read as follows:

§ 484.4 Personnel qualifications.

* * * * *

Speech-language pathologist. A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(a) Is licensed as a speech-language pathologist by the State in which the individual furnishes such services; or

(b) In the case of an individual who furnishes services in a State which does not license speech-language pathologists:

(1) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience);

(2) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(3) Successfully completed a national examination in speech-language pathology approved by the Secretary.

■ 7. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b)(1) and (d)(1) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235, and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 8. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, and 1395hh); Pub. L. 110–149, 121 Stat. 1819.

■ 9. Section 488.845 is amended by adding paragraph (h) to read as follows:

§ 488.845 Civil money penalties.

* * * * *

(h) *Review of the penalty.* When an administrative law judge or state hearing officer (or higher administrative review authority) finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTCIPATION OF ICFS/IID AND CERTAIN NFS IN THE MEDICAID PROGRAM

■ 10. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–7j, and 1395hh).

■ 11. Section 498.3 is amended by revising paragraphs (b)(13) and (14)(i) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at paragraph (d)(12) of this section for SNFs, NFs, and HHAs, the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406 or 488.820 of this chapter, but not the determination as to which sanction was imposed. The scope of review on the imposition if a civil money penalty is specified in §§ 488.438(e) and 488.845(h) of this chapter.

(14) * * *

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in § 488.438(e) of this chapter and for HHAs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in § 488.845(h) of this chapter); or

* * * * *

■ 12. Section 498.60 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 498.60 Conduct of hearing.

* * * * *

(c) * * *

(1) The scope of review is as specified in §§ 488.438(e) and 488.845(h) of this chapter; and

(2) CMS' determination as to the level of noncompliance of a SNF, NF, or HHA must be upheld unless it is clearly erroneous.

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 28, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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