

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 431, 484, 488, 489, and 498

[CMS–1358–P]

RIN 0938–AR18

Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the Home Health Prospective Payment System (HH PPS) rates, including the national standardized 60-day episode rates, the national per-visit rates, the low-utilization payment amount (LUPA), and outlier payments under the Medicare prospective payment system for home health agencies effective January 1, 2013. This rule also proposes requirements for the Hospice quality data reporting program. This proposed rule would also establish requirements for unannounced, standard and extended surveys of home health agencies (HHAs) and provide a number of alternative (or intermediate) sanctions that could be imposed if HHAs were out of compliance with Federal requirements. This proposed rule would set forth alternative sanctions that could be imposed instead of or in addition to termination of the HHA's participation in the Medicare program, which could remain in effect up to a maximum of 6 months, until the HHA achieved compliance with the HHA Conditions of Participation (CoPs), or until the HHA's provider agreement was terminated.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1358–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

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Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1358–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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3. *By express or overnight mail.* You may send written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1358–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

Kristine Chu, (410) 786–8953, for information about the HH payment reform study and report.

Robin Dowell, (410) 786–0060, for information about HH and Hospice quality improvement and reporting.

Kim Evans, (410) 786–0009, for information about HH therapy policies.

Mollie Knight, (410) 786–7948, for information about the HH market basket.

Hillary Loeffler, (410) 786–0456, for information about the HH PPS.

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

Patricia Sevast, 410–786–8135 and Peggye Wilkerson, 410–786–4857, for survey and enforcement requirements for HHAs.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

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Regulations Text

Acronyms

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

ACH LOS Acute Care Hospital Length of Stay
 ADL Activities of Daily Living
 APU Annual Payment Update
 BBA Balanced Budget Act of 1997, Pub. L. 105–33
 BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
 CAD Coronary Artery Disease
 CAH Critical Access Hospital
 CBSA Core-Based Statistical Area
 CHF Congestive Heart Failure
 CMI Case-Mix Index
 CMS Centers for Medicare and Medicaid Services
 CoPs Conditions of Participation
 COPD Chronic Obstructive Pulmonary Disease
 CVD Cardiovascular Disease
 CY Calendar Year

DM Diabetes Mellitus
 DRA Deficit Reduction Act of 2005, Pub. L. 109–171, enacted February 8, 2006
 FDL Fixed Dollar Loss
 FI Fiscal Intermediaries
 FR **Federal Register**
 FY Fiscal Year
 HCC Hierarchical Condition Categories
 HCIS Health Care Information System
 HH Home Health
 HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
 HH PPS Home Health Prospective Payment System
 HHAs Home Health Agencies
 HHRG Home Health Resource Group
 HIPPS Health Insurance Prospective Payment System
 IH Inpatient Hospitalization
 IRF Inpatient Rehabilitation Facility
 LTCH Long-Term Care Hospital
 LUPA Low Utilization Payment Amount
 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 Areas
 MSS Medical Social Services
 NRS Non-Routine Supplies
 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
 PAC-PRD Post-Acute Care Payment Reform Demonstration
 PEP Partial Episode Payment Adjustment
 PT Physical Therapy
 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
 SLP Speech Language Pathology Therapy
 SNF Skilled Nursing Facility
 UMRA Unfunded Mandates Reform Act of 1995.

I. Executive Summary

A. Purpose

This rule proposes updates to the payment rates for home health agencies (HHAs) for Calendar Year (CY) 2013 as required under section 1895(b) of the Social Security Act (the Act). The proposed update to the prospective payment system addresses the market basket update, case-mix adjustments due to variation in costs among different units of services, adjustments for geographic differences in wage levels, outlier payments, the submission of quality data, and additional payments for services provided in rural areas.

B. Summary of the Major Provisions

In this proposed rule, we use the methods described in the CY 2012 HH PPS final rule (76 FR 68526) to update the prospective payment rates for CY 2013 using a proposed rebased and revised market basket described in section III.C.1 of this rule. This rule discusses the proposed case-mix up-coding adjustment. In addition, we propose additional regulatory flexibility regarding therapy documentation and reassessments as well as face-to-face encounter requirements. We also provide an update on the transition plan for ICD–10 and the home health study concerning home health care access. In addition, this rule proposes new requirements concerning the hospice quality reporting program. Lastly, this proposed rule would establish requirements concerning HHAs.

C. Summary of Costs and Benefits

Provision description	Total costs	Total benefits	Transfers
CY 2013 HH PPS payment rate update.	N/A	The benefits of this proposed rule include paying more accurately for the delivery of Medicare home health services, providing additional regulatory flexibility for HHAs to comply with therapy requirements and face-to-face encounter documentation requirements, and establishing alternative (or intermediate) sanctions that may be imposed when HHAs are out of compliance with Federal requirements.	The overall economic impact of this proposed rule is an estimated \$20 million in decreased payments to HHAs.

Provision description	Total costs	Total benefits	Transfers
Survey and Certification Requirements.	The components of the rule which address survey and certification requirements do not represent new costs with the exception of the Informal Dispute Resolution process (IDR). These requirements codify Survey and Certification policies which were implemented between 1987 and 2011. We estimate that the costs associated with the IDRs will not be significantly greater than current actions related to termination actions.	The overall benefit of this rule is the expected increase in provider participation in discussions with the State Survey Agency or CMS Regional Offices related to survey findings via the IDR.	
Enforcement Requirements	We estimate a onetime \$2 million expense to modify internal systems to monitor Civil Monetary Penalties. There will also be annual operating expenses associated with maintaining the system, training surveyors and troubleshooting issues of \$335,972.	HHAs will be provided incentives to maintain or regain compliance with the HHA Conditions of Participation through measures other than termination.	
CMP Disbursement and Cost of Surveys.	This proposed rule would provide that State Medicaid programs share in the cost of HHA surveys. The cost ratio would be calculated at 63 percent for the Medicare program and 37 percent for the Medicaid program. The projected HHA survey budget for FY 2013 is \$39.9 million and FY 2014 at \$45.7 million. The anticipated State Medicaid share is \$3.7 million and \$4.2 million respectively (minus Federal match).	This is in compliance with OMB Circular A-87.	

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 a 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. 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) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental

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

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH market basket percentage increase is reduced 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 Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. 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 medical 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 Medicare prospective payment system for HHAs for CY 2008. The CY 2008 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 in the national standardized 60-day episode payment rates and the NRS conversion factor. 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.

For CY 2012, we published the November 4, 2011 final rule (76 FR 68526) (hereinafter referred to as the CY 2012 HH PPS final rule) that set forth the update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HH services. In addition, as discussed in the CY 2012 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. To fully account for the 19.03 percent nominal case-mix growth which was identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and 1.32 percent payment reduction for CY 2013.

III. Provisions of the Proposed Rule

A. Case-Mix Measurement

Every year since the HH PPS CY 2008 proposed rule, we have stated in HH PPS rulemaking that we would continue to monitor case-mix changes in the HH PPS and to update our analysis to measure change in case-mix, both real changes in case-mix and changes which are unrelated to changes in patient acuity (nominal). We have continued to monitor case-mix changes, and our latest analysis continues to support the need to make payment adjustments to account for nominal case-mix growth.

Before measuring nominal case-mix growth, we examined the total case-mix growth every year from 2000 to 2010. Our latest analysis indicates that there was about a 1 percent increase in the

average case-mix weight from 2009 to 2010. Specifically, the 2009 average case-mix was 1.3435 and the 2010 average case-mix was 1.3578. We also examined the change in the reporting of secondary diagnoses on OASIS from 2009 to 2010 and have observed an increase in the reporting of secondary diagnoses from 2009 to 2010, thereby contributing to the growth in total case-mix. In addition, we looked at the change in the distribution of episodes by number of therapy visits from 2009 to 2010 and saw that the percentage of non-therapy episodes decreased by 1.56 percentage points and the percentage of episodes with therapy increased at all levels of therapy, thereby contributing to the growth in overall case-mix from 2009 to 2010. Our analysis also showed a continued increase in the percentage of episodes with 14–19 and 20+ therapy visits.

For the remainder of this section, we will discuss our latest analysis of real and nominal case-mix change.

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 not related to actual changes in patient characteristics over time. Nominal case-mix growth was assessed and reported in CY 2008, CY 2011, and CY 2012 rulemaking, and payment reductions to the base rate were implemented to account for the nominal case-mix growth observed.

In CY 2008 rulemaking, to assess nominal case-mix growth, we first estimated real case-mix growth, changes in case-mix which are related to changes in patient characteristics, using a regression-based, predictive model of individual case-mix weights. The predictive model contained measures of patients' demographic characteristics, clinical status, inpatient history, and Part A Medicare costs in the time period leading up to their home health episodes. The regression coefficients for the predictive model were developed using 2000 as a base year and were applied to episodes from 2005, allowing for estimation of the change in real case-mix. We then determined the nominal case-mix growth from 2000 to 2005 using the regression model-predicted real case-mix change and the total case-mix change for the time period of interest.

Our analysis indicated that there was a 12.78 percent increase in overall case-mix from 2000 to 2005 and 8.03 percent of that overall observed case-mix change was identified as real case-mix change. As a result of our analysis, we adjusted the 12.78 percent of total change in case-mix downward by 8.03 percent to

get a final nominal case-mix change measure of 11.75 percent ($0.1278 * (1 - 0.0803) = 0.1175$). To account for the 11.75 percent increase in nominal case-mix, we implemented a payment reduction of 2.75 percent each year for 3 years, beginning in 2008, and we planned to implement a payment reduction of 2.71 percent in CY 2011.

Since the publication of the HH PPS CY 2008 proposed rule (72 FR 25395), we have continued to monitor case-mix changes in the HH PPS, and in CY 2011 rulemaking we updated our analysis to measure more recent changes in real and nominal case-mix. In CY 2011 rulemaking, to accommodate the shift to the 153-group system in 2008, we developed two regression-based models to assess nominal case-mix growth from 2000 to 2008. One model was developed using 2000 as a base year and the 80 grouper case-mix system. The regression coefficients in the model were applied to 2007 data to determine the change in real case-mix from 2000 to 2007. The second model was developed using 2008 as a base year and the 153 grouper case-mix system. The regression coefficients in the model were applied to 2007 data to determine the change in real case-mix from 2007 to 2008. The data from both of the models were then used to calculate the overall real case-mix change from 2000 to 2008. Our analysis indicated that there was a 19.40 percent increase in overall case-mix from 2000 to 2008 and 10.07 percent of that overall observed case-mix change was identified as real case-mix change. Consequently, as a result of our analysis, we identified a 17.45 percent nominal increase in case-mix ($0.1940 * (1 - 0.1007) = 0.1745$) from 2000 to 2008. In other words, there was a growth in case-mix of 17.45 percent that was unrelated to differences in patient characteristics, reflecting changes in coding documentation and other behavioral responses to the home health prospective payment system rather than the treatment of more resource-intensive patients. To fully account for the 17.45 percent nominal case-mix growth identified from 2000 to 2008, in the CY 2011 proposed rule, we proposed a 3.79 percent payment reduction (replacing the planned 2.71 percent payment reduction) in CY 2011 and an additional 3.79 percent payment reduction in CY 2012.

We received many comments on our CY 2011 HH PPS proposed rule that criticized our methodology for assessing real and nominal case-mix change. In the CY 2011 HH PPS final rule, we implemented the proposed payment reduction of 3.79 percent to the national standardized episode rate in CY 2011.

However, due to the extensive comments we received, we deferred finalizing a payment reduction for CY 2012 until further study of the case-mix data and methodology was completed.

To assess the validity of the criticisms we received about our models to measure real and nominal case-mix change, we procured an independent review of our methodology by a team at Harvard University led by Dr. David Grabowski. The review included an examination of the predictive regression models and data used in CY 2011 rulemaking, and further analysis consisting of extensions of the model to allow a closer look at nominal case-mix growth by categorizing the growth according to provider types and subgroups of patients.

When reviewing the model, the Harvard team found that overall, our models were robust. However, one area of potential refinement to our models that the Harvard team suggested was to incorporate variables derived from Hierarchical Condition Categories (HCC) data, which is used by CMS to risk-adjust payments to managed care organizations in the Medicare program.

During CY 2012 rulemaking, based on Dr. Grabowski and his team's recommendation and our previous consideration to incorporate HCC data in our models to assess real case-mix change, we explored the effects of adding HCC patient classification data into our models. For our analysis of real and nominal case-mix growth from 2000 to 2009, we incorporated the HCC community scores, HCC demographic variables, and disease indicator variables into our models. It should be noted that we enhanced our models with HCC data starting in 2005 due to the availability of HCC data in our analytic files.

To use the HCC data as well as accommodate the shift to the 153-group system in 2008, we analyzed real case-mix change for 3 different periods, from 2000 to 2005, from 2005 to 2007, and from 2007 to 2009. The real case-mix change from 2000 to 2005 was assessed using the same variables used in the model described in the CY 2011 HH PPS proposed rule (75 FR 43238). The real case-mix change from 2005 to 2007 and from 2007 to 2009 was assessed using the pre-existing variable set plus additional information from the HCC variables. To determine the amount of real case-mix change from 2000 to 2009 (0.0390 case-mix units), we added the measured real change in case-mix units for each of the 3 periods (0.0207 case-mix units for 2000 to 2005, 0.0061 case-mix units for 2005 to 2007, and 0.0122 case-mix units for 2007 to 2009). We

then compared the real change in case-mix (0.0390 case-mix units) for 2000 to 2009 to the total change in case-mix from 2000 to 2009 (0.2476 case-mix units). The total change in case-mix from 2000 to 2009 was calculated as the difference between the average case-mix in 2000 (1.0959) and the average case-mix in 2009 (1.3435). Based on the results from our models, we estimated 15.76 percent ($0.0390/0.2476 = 0.1576$) of the total case-mix change as real. It should be noted that there is a 0.01 percentage point difference between the calculated and actual value due to the fact that 0.0390 and 0.2476 are rounded figures. When taking into account the total case-mix change from 2000 to 2009 of 22.59 percent ($(1.3435 - 1.0959)/1.0959 = 0.2259$) and the 15.76 percent of total case-mix change estimated as real from 2000 to 2009, we obtained a final nominal case-mix change measure of 19.03 percent ($0.2259 * (1 - 0.1576) = 0.1903$) from 2000 to 2009.

This year, we updated our estimates of real and nominal case-mix growth using 2010 data. To determine the amount of real case-mix growth from 2000 to 2010, we needed to obtain an estimate of real case-mix change for 2007 to 2010. We obtained this value using the same model as the one described in CY 2012 rulemaking, which was developed using 2009 data. We note that when developing an estimate of real case-mix change for 2007 to 2010, we used 2010 data for all of the variables in the model except for the living arrangement variables. A crosswalk could not be built from OASIS C to OASIS B1 for the living arrangement variables and therefore we predicted the 2010 value based on trends from 2007 to 2009. After obtaining the estimate of real case-mix change for 2007 to 2010 (0.0150 case-mix units), we added this estimate to the 2000 to 2005 estimate of real case-mix change (0.0207 case-mix units) and the 2005 to 2007 estimate of real case-mix change (0.0061 case-mix units). After adding together the estimated real case-mix change in case-mix units for the three periods, the total estimated change in real case-mix from 2000 to 2010 was 0.0418 ($0.0207 + 0.0061 + 0.0150 = 0.0418$). Given that the total change in case-mix from 2000 to 2010 was 0.2619 case-mix units ($1.3578 - 1.0959 = 0.2619$), we estimate that 15.97 percent of the total percentage change in the national average case-mix weight since the interim payment system baseline through 2010 is due to change in real case-mix ($0.0418/0.2619 = 0.1597$). It should be noted that there is a 0.01 percentage point difference

between the calculated and actual value due to the fact that 0.0418 and 0.2619 are rounded figures. When taking into account the total measure of case-mix change (23.90 percent; see Table 1) 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 ($0.2390 * (1 - 0.1597) = 0.2008$). Please see Table 1 for additional information about the calculations used to make the real and nominal case-mix change estimates from 2000 to 2010.

Our estimates of real and nominal case-mix change are consistent with past results. Most of the case-mix change has been due to improved coding, coding practice changes, and other behavioral responses to the prospective payment system, such as increased use of high therapy treatment plans.

TABLE 1—SUMMARY OF REAL AND NOMINAL CASE-MIX CHANGE ESTIMATES: 2000–2010

Measure	Model
Actual case-mix: 2000	1.0959
Actual case-mix: 2010	1.3578
Total change in case-mix	0.2619
Total percentage change	23.90%
Estimated real change in case-mix ..	0.0418
Percent of total change estimated as real	15.97%
Percent of total change estimated as nominal (creep)	84.03%
Real case-mix percent increase	3.82%
Nominal case-mix percent increase ..	20.08%

As we described earlier in this proposed rule, our CY 2008 HH PPS final rule finalized a reduction over 4 years in the national standardized 60-day episode payment rates to account for a large increase in case-mix from 2000 to 2005 which we determined was not related to treatment of more intense patients. We implemented a 2.75 percent reduction each year for 2008, 2009, and 2010 and planned to reduce payments by 2.71 percent in 2011. In CY 2011 rulemaking, we updated our analysis of nominal case-mix growth through 2008 and determined that there was 17.45 percent nominal case-mix growth from 2000 to 2008. Therefore, we proposed and finalized an increase in the planned 2.71 percent reduction to 3.79 percent for CY 2011. For the CY 2012 proposed rule, after updating our models to incorporate HCC data, we determined that there was a 19.03 percent nominal case-mix change from 2000 to 2009. To account for the nominal case-mix growth through 2009, we finalized a 3.79 percent payment

reduction to the national standardized 60-day episode rates for nominal case-mix change for CY 2012 and a 1.32 percent payment reduction to the rates in CY 2013.

When including the latest data available, we determined that there was a 20.08 percent nominal case-mix change from 2000 to 2010. To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which has been accounted for in previous payment reductions, we estimate that the percentage reduction to the national standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. We considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, and seek comments on that proposal, rather than moving forward with the 1.32 percent reduction promulgated in last year's CY 2012 HH PPS final rule. However for CY 2013, we propose to move forward with the 1.32 percent payment reduction to the national standardized 60-day episode rates as promulgated in the CY 2012 HH PPS Final Rule (76 FR 68532). Analysis, to date, would seem to indicate a high likelihood of continued growth in nominal case-mix going forward. As such, we will continue to monitor both real and nominal case-mix change and make updates as appropriate. CMS will consider any and all analyses as it continues to address the issue of the increase in nominal case-mix in future rulemaking.

B. Outlier Policy

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 home health (HH) care needs. Prior to the enactment of the Affordable Care Act, this section of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 2000 final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode. The outlier threshold for each case-mix group or

partial episode payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a 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 fixed dollar loss amount. The proportion of additional costs paid as outlier payments is referred to as the loss-sharing ratio.

2. Regulatory Update

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 have continued to do 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 expenditures.)

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 low utilization payment adjustment (LUPA) add-on payment amount, and the non-routine supplies (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.

3. Statutory Update

As outlined 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, "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 redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising it to state that the Secretary, "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 with respect to 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 get there, 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.

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

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio and, therefore, increase outlier payments for 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). In the past, we have used a value of 0.80 for the loss-sharing ratio, which is relatively high, but 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. We are not proposing a change to the loss-sharing ratio in this proposed rule. 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. 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, 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.

Based on simulations using CY 2010 claims data, we estimate that outlier payments in 2012 will comprise approximately 2.12 percent of total HH PPS payments. Simulations based on CY 2009 claims data completed for the CY 2012 HH PPS final rule (76 FR 68528) suggested that outlier payments in 2011 would comprise approximately 2.14 percent of total HH PPS payments. As such, our simulations suggest outlier payments as a percentage total HH payments holding steady in CY 2009 and CY 2010. However, we are proposing no change to the FDL, in part because we have not been able to verify these projections in our paid claims files since we implemented the 10 percent agency-level cap on outlier payments on January 1, 2010. Two claims processing errors were identified in our implementation of the 10 percent agency-level cap on outlier payments. These errors resulted in inaccuracies in outlier payment amounts in our paid claims files for CY 2010 and 2011. One error allows for certain HHAs to be paid beyond the cap, resulting in overpayments. The other applies the cap to HHAs who have not reached it yet, resulting in underpayments. System changes are currently underway, and thus the CY 2010 data file used in our analysis for this proposed rule reflects outlier payments with these claims processing errors. Furthermore, another consideration in proposing no change to the FDL is our implementation in the CY 2012 HH PPS final rule of changes to the case-mix weights. The changes put more weight on non-therapy cases that typically are more likely to receive outlier payments. The data showing the effects of the changes to the case-mix weights on outlier payments will not be available for analysis until next year. In

the final rule, we will update our estimate of the FDL ratio using the best analysis the most current and complete year of HH PPS data.

5. Outlier Relationship to the HH Payment Study

As we discuss later in this proposed rule, section 3131(d) of the Affordable Care Act requires CMS to conduct a study and report on developing HH payment revisions that will ensure access to care and payment for HH patients with high severity of illness. Our Report to Congress containing this study's recommendations is due no later than March 1, 2014. Section 3131(d)(1)(A)(iii) of the Affordable Care Act, in particular, states that this study may include analysis of potential revisions to outlier payments to better reflect costs of treating Medicare beneficiaries with high levels of severity of illness.

C. CY 2013 Rate Update

1. Rebasing and Revising of the Home Health Market Basket

a. Background

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2013 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.

Effective for cost reporting periods beginning on or after July 1, 1980, we developed and adopted an HHA input price index (that is, the home health "market basket"). Although "market basket" technically describes the mix of goods and services used to produce home health care, this term is also commonly used to denote the input price index derived from that market basket. Accordingly, the term "home health market basket" used in this document refers to the HHA input price index.

The percentage change in the home health market basket reflects the average change in the price of goods and services purchased by HHAs in providing an efficient level of home health care services. We first used the home health market basket to adjust HHA cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish reasonable cost home health care. This approach linked the increase in the cost limits to the efficient utilization of resources. For a greater discussion on the home health market basket, see the notice with comment period published in the February 15,

1980 **Federal Register** (45 FR 10450, 10451), the notice with comment period published in the February 14, 1995 **Federal Register** (60 FR 8389, 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344, 34347). Beginning with the FY 2002 HH PPS payments, we used the home health market basket to update payments under the HH PPS. We last rebased the home health market basket effective with the CY 2008 update. For more information on the HH PPS home health market basket, see our proposed rule published in the May 4, 2007 **Federal Register** (72 FR 25435–25442).

The home health market basket is a fixed-weight Laspeyres-type price index; its weights reflect the cost distribution for the base year while current period price changes are measured. The home health market basket is constructed in three major steps. First, a base period is selected and total base period expenditures are estimated for mutually exclusive and exhaustive spending categories based upon the type of expenditure. Then the proportion of total costs that each spending category represents is determined. These proportions are called cost or expenditure weights.

The second step essential for developing an input price index is to match each expenditure category to an appropriate price/wage variable, called a price proxy. These proxy variables are mainly drawn from publicly available statistical series published on a consistent schedule, preferably at least quarterly.

In the third and final step, the price level for each spending category is multiplied by the expenditure weight for that category. The sum of these products for all cost categories yields the composite index level in the market basket in a given year. Repeating the third step for other years will produce a time series of market basket index levels. Dividing one index level by an earlier index level will produce rates of growth in the input price index.

We describe the market basket as a fixed-weight index because it answers the question of how much more or less it would cost, at a later time, to purchase the same mix of goods and services that was purchased in the base period. As such, it measures "pure" price changes only. The effects on total expenditures resulting from changes in the quantity or mix of goods and services purchased subsequent to the base period are, by design, not considered.

b. Rebasing and Revising the Home Health Market Basket

We believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. We based the cost category weights in the current home health market basket on CY 2003 data. We are proposing to rebase and revise the home health market basket to reflect CY 2010 Medicare cost report (MCR) data, the latest available and most complete data on the actual structure of HHA costs.

The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. The term "rebasing" means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from CY 2003 to CY 2010) without making any other major changes to the methodology. The term "revising" means changing data sources, cost categories, and/or price proxies used in the input price index.

For this proposed rebasing and revising, we modified the wages and salaries and benefits cost categories to reflect revised occupational groupings of BLS Occupational Employment Statistics (OES) data of HHAs. As a result of the revised groupings, we are also proposing changes to the wage and benefit price proxies used in the HH market basket. We are also proposing to break out the Administration and General (A&G), Operations and Maintenance, and All Other (residual) cost category weight into more detailed cost categories, based on the 2002 Benchmark U.S. Department of Commerce, Bureau of Economic Analysis (BEA) Input-Output (I-O) Table for HHAs. We are proposing to revise the price proxies for the Insurance and Transportation cost categories. Finally, we are proposing the use of four new price proxies for the four additional cost categories.

The major cost weights for this proposed revised and rebased home health market basket are derived from the Medicare Cost Reports (MCR) data for freestanding HHAs, whose cost reporting period began on or after January 1, 2010 and before January 1, 2011. Using this methodology allowed our sample to include HHA facilities with varying cost report years including, but not limited to, the Federal fiscal or calendar year. We refer to the market basket as a calendar year market basket because the base period for all price proxies and weights are set to CY 2010.

We propose to maintain our policy of using data from freestanding HHAs because we have determined that they better reflect HHAs' actual cost structure. Expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution. Due to the method of allocation, total expenses will be correct, but the individual components' expenses may be skewed; therefore, if data from hospital-based HHAs were included, the resulting cost structure could be unrepresentative of the average HHA costs.

Data on HHA expenditures for nine major expense categories (Wages and Salaries, Employee Benefits, Transportation, Operation and Maintenance, A&G, Professional Liability Insurance (PLI), Fixed Capital, Movable Capital, and a residual "All Other") were tabulated from the CY 2010 Medicare HHA cost reports. As prescription drugs and DME are not payable under the HH PPS, we excluded those items from the home health market basket and from the expenditures. Expenditures for contract services were also tabulated from these CY 2010 Medicare HHA cost reports and allocated to Wages and Salaries, Employee Benefits, A&G, and Other Expenses. After totals for these cost categories were edited to remove reports where the data were deemed unreasonable (for example, when total costs were not greater than zero), we then determined the proportion of total costs that each category represents. The proportions represent the major rebased home health market basket weights.

Next, we disaggregated the costs for the A&G, Operations and Maintenance and "All Other" cost weights using the latest available (2002 Benchmark) U.S. Department of Commerce, Bureau of

Economic Analysis (BEA) Input-Output (I-O) Table, from which we extracted data for HHAs. The BEA I-O data, which are updated at 5-year intervals, were most recently described in the Survey of Current Business article, "Benchmark Input-Output Accounts of the U.S., 2002" (December 2002). These data were aged from 2002 to 2010 using relevant price changes. The methodology we used to age the data applied the annual price changes from the price proxies to the appropriate cost categories. We repeated this practice for each year. This methodology reflects a slight revision from the methodology used to derive the 2003-based HHA market basket index. For the 2003-based index, we only disaggregated the A&G and "All Other" cost categories using BEA I-O data. For the 2010-based index, we are proposing to also disaggregate the Operations and Maintenance cost categories using the BEA I-O data. Our proposal is based on our examination of the MCR data which indicated that some providers may be including some operations and maintenance costs in the A&G category and/or other cost categories. The Operations and Maintenance cost category (which we previously proxied with the CPI for Fuel and Other Utilities) from the MCR showed a decrease in the cost weight obtained directly from the MCR data from 2003 to 2010, despite rapid increases in utility costs over this time period. The revised method would rely on the 2002 I-O data, aged by the relevant price proxy, to determine the Utilities cost weight. The resulting methodology shows an increase in the Utilities cost weight over the same time period, which we believe to be a more reasonable result. We believe this change in the methodology for estimating utility costs for HHAs better

reflects the 2010 cost structures of HHAs.

This process resulted in the identification of 16 separate cost categories, which is four more cost categories than presented in the 2003-based home health market basket. The additional cost categories (Administrative and Support Services, Financial Services, Medical Supplies, and Rubber and Plastics) stem from further disaggregating the Other Products and Other Services cost categories presented in the 2003-based index into more detail. The Administrative and Support Services cost weight would include expenses for a range of day-to-day office administrative services including but not limited to billing, recordkeeping, mail routing, and reception services. The Financial Services cost weight would reflect expenses for services including but not limited to banking services and security and commodity brokering. The Medical Supplies cost weight would reflect expenses for medical and surgical instruments as, well as laboratory analysis equipment. The Rubber and Plastics cost weight would reflect expenses for products such as plastic trash cans, and carpeting. We are proposing these additional cost categories in order to proxy price inflation in a more granular fashion. We provide our proposed price proxies in more detail below.

The differences between the major categories for the proposed 2010-based index and those used for the current 2003-based index are summarized in Table 2. We have allocated the Contract Services weight to the Wages and Salaries Employee Benefits, A&G, and Other Expenses cost categories in the proposed 2010-based index as we did in the 2003-based index.

TABLE 2—COMPARISON OF 2003-BASED AND PROPOSED 2010-BASED HOME HEALTH MARKET BASKETS MAJOR COST CATEGORIES AND WEIGHTS

Cost categories	2003-Based home health market basket	Proposed 2010-based home health market basket
Wages and Salaries, including allocated contract services' labor	64.484	66.325
Employee Benefits, including allocated contract services' labor	12.598	12.210
All Other Expenses including allocated contract services' labor	22.918	21.465
Total	100.000	100.000

The complete proposed 2010-based cost categories and weights are listed in Table 3.

TABLE 3—COST CATEGORIES, WEIGHTS, AND PRICE PROXIES IN PROPOSED 2010-BASED HOME HEALTH MARKET BASKET

Cost categories	Weight	Price proxy
Compensation, including allocated contract services' labor	78.535	
Wages and Salaries, including allocated contract services' labor	66.325	Proposed Home Health Occupational Wage Index (2010).
Employee Benefits, including allocated contract services' labor ...	12.210	Proposed Home Health Occupational Benefits Index (2010).
Operations & Maintenance	1.002	CPI-U Fuel & Other Utilities.
Professional Liability Insurance	0.375	CMS Physician Professional Liability Insurance Index.
Administrative & General & Other Expenses including allocated contract services' labor.	15.381	
Administrative Support	0.699	ECI for Compensation for Office and Administrative Services (Private).
Financial Services	1.398	ECI for Compensation for Financial Services (Private).
Medical Supplies	1.278	PPI for Medical Surgical & Personal Aid Devices.
Rubber & Plastics	1.226	PPI for Rubber & Plastic Products.
Telephone	0.881	CPI-U Telephone Services.
Postage	0.279	CPI-U Postage.
Professional Fees	5.811	ECI for Compensation for Professional and Related Workers (Private).
Other Products	1.439	PPI Finished Goods less Food and Energy.
Other Services	2.370	ECI for Compensation for Service Occupations (Private).
Transportation	2.545	CPI-U Transportation.
Capital-Related	2.162	
Fixed Capital	1.532	CPI-U Owner's Equivalent Rent.
Movable Capital	0.630	PPI Machinery & Equipment.
Total	100.000	**

** Figures may not sum to total due to rounding.

After we computed the CY 2010 cost category weights for the proposed rebased home health market basket, we selected the most appropriate wage and price indexes to proxy the rate of change for each expenditure category. With the exception of the price index for insurance costs, the proposed price proxies are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. They are not affected by shifts in skill mix. ECIs are superior to average hourly earnings as price proxies for input price indexes for two reasons: (a) They measure pure price change; and (b) they are available by occupational groups, not just by industry.

- *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Consumer price indexes are used when the expenditure is more similar to that of a purchase at the retail level rather than at the wholesale level, or if no appropriate Producer Price Indexes (PPIs) were available.

- *Producer Price Indexes*—PPIs measures average changes in prices received by domestic producers for their

goods and services. PPIs are used to measure price changes for goods sold in other than retail markets. For example, a PPI for movable equipment is used rather than a CPI for equipment. PPIs in some cases are preferable price proxies for goods that HHAs purchase at wholesale levels. These fixed-weight indexes are a measure of price change at the producer or at the intermediate stage of production.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in way that can be replicated. Low sampling variability is desirable because it indicates that sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and therefore it is important the underlying price proxies be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly helps ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated

frequently because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected by us to be proposed in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

As part of the revising and rebasing of the home health market basket, we are proposing to revise and rebase the home health blended Wage and Salary index and the home health blended Benefits index. We would use these blended indexes as price proxies for the Wages and Salaries and the Employee Benefits portions of the proposed 2010-based home health market basket, as we did in the 2003-based home health market basket. A more detailed discussion is provided below.

c. Price Proxies Used To Measure Cost Category Growth

- *Wages and Salaries* For measuring price growth in the 2010-based home health market basket, we are proposing

to apply six price proxies to six occupational subcategories within the Wages and Salaries component, which would reflect the HHA occupational mix. This is the same approach used for the 2003-based index as there is not a published wage proxy for home health care workers that reflects only wage changes and not both wage and skill mix changes.

The 2003-based blended wage index was comprised of four occupational subcategories proxied by five wage proxies. For the 2010 blended wage index, we are proposing to further disaggregate the service workers occupations into health and social assistance service and other service occupational groups. We are also proposing to explicitly disaggregate professional and technical (P&T)

workers into health-related P&T and non health-related P&T workers. We are proposing to continue to use the National Industry-Specific Occupational Employment and Wage estimates for North American Industrial Classification System (NAICS) 621600, Home Health Care Services, published by the BLS Office of Occupational Employment Statistics (OES) as the data source for the cost shares of the home health specific blended wage and benefits proxy. This is the same data source that was used for the 2003-based HHA blended wage and benefit proxies; however, we are proposing to use the May 2010 estimates in place of the November 2003 estimates. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey

can be found at http://www.bls.gov/oes/current/oes_tec.htm.

The needed data on HHA expenditures for the six occupational subcategories (managerial, health-related P&T, non health-related P&T, health and social assistance service, other service occupations, and administrative/clerical) for the wages and salaries component were tabulated from the May 2010 OES data for NAICS 621600, Home Health Care Services. This is a refinement to the four categories used for the 2003-based wage proxy. Table 4 compares the proposed 2010 occupational assignments of the six CMS designated subcategories to the 2003 occupational assignments of the four CMS designated subcategories.

TABLE 4—PROPOSED 2010 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2003 OCCUPATIONAL ASSIGNMENTS FOR CMS HH WAGE COMPOSITE INDEX

2010 Proposed Occupational Groupings		2003 Occupational Groupings	
Group 1	Management	Group 1	Management
11-0000	Management Occupations	11-0000	Management Occupations.
Group 2	Non-Health Professional & Technical	Group 2	Professional & Technical
13-0000	Business and Financial Operations Occupations	13-0000	Business and Financial Operations Occupations.
15-0000	Computer and Mathematical Science Occupations	15-0000	Computer and Mathematical Science Occupations.
17-0000	Architecture and Engineering Occupations	17-0000	Architecture and Engineering Occupations.
19-0000	Life, Physical, and Social Science Occupations	19-0000	Life, Physical, and Social Science Occupations.
23-0000	Legal Occupations	21-0000	Community and Social Services Occupations.
25-0000	Education, Training, and Library Occupations	23-0000	Legal Occupations.
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations.	25-0000	Education, Training, and Library Occupations.
Group 3	Health-Related Professional & Technical	27-0000	Arts, Design, Entertainment, Sports, and Media Occupations.
29-1021	Dentists, General	29-0000	Healthcare Practitioners and Technical Occupations.
29-1031	Dietitians and Nutritionists	33-0000	Protective Service Occupations.
29-1051	Pharmacists	35-0000	Food Preparation and Serving Related Occupations.
29-1062	Family and General Practitioners	37-0000	Building and Grounds Cleaning and Maintenance Occupations.
29-1063	Internists, General	41-0000	Sales and Related Occupations.
29-1069	Physicians and Surgeons, All Other	49-0000	Installation, Maintenance, and Repair Occupations.
29-1071	Physician Assistants	51-0000	Production Occupations.
29-1111	Registered Nurses	53-0000	Transportation and Material Moving Occupations.
29-1122	Occupational Therapists.		
29-1123	Physical Therapists.		
29-1125	Recreational Therapists.		
29-1126	Respiratory Therapists.		
29-1127	Speech-Language Pathologists.		
29-1129	Therapists, All Other.		
29-1199	Health Diagnosing and Treating Practitioners, All Other.		
Group 4	Other Service Workers	Group 3	Service Workers
33-0000	Protective Service Occupations	31-0000	Healthcare Support Occupations.
35-0000	Food Preparation and Serving Related Occupations	39-0000	Personal Care and Service Occupations.
37-0000	Building and Grounds Cleaning and Maintenance Occupations.		
39-0000	Personal Care and Service Occupations.		
41-0000	Sales and Related Occupations.		
49-0000	Installation, Maintenance, and Repair Occupations.		
51-0000	Production Occupations.		
53-0000	Transportation and Material Moving Occupations.		

TABLE 4—PROPOSED 2010 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2003 OCCUPATIONAL ASSIGNMENTS FOR CMS HH WAGE COMPOSITE INDEX—Continued

2010 Proposed Occupational Groupings		2003 Occupational Groupings	
Group 5	Health & Social Service Workers		
21–0000	Community and Social Services Occupations.		
29–2011	Medical and Clinical Laboratory Technologists.		
29–2012	Medical and Clinical Laboratory Technicians.		
29–2021	Dental Hygienists.		
29–2032	Diagnostic Medical Sonographers.		
29–2034	Radiologic Technologists and Technicians.		
29–2041	Emergency Medical Technicians and Paramedics.		
29–2051	Dietetic Technicians.		
29–2052	Pharmacy Technicians.		
29–2054	Respiratory Therapy Technicians.		
29–2061	Licensed Practical and Licensed Vocational Nurses.		
29–2071	Medical Records and Health Information Technicians.		
29–2099	Health Technologists and Technicians, All Other.		
29–9012	Occupational Health and Safety Technicians.		
29–9099	Healthcare Practitioner and Technical Workers, All Other.		
31–0000	Healthcare Support Occupations.		
Group 6	Administrative	Group 4	Administrative
43–0000	Office and Administrative Support Occupations	43–0000	Office and Administrative Support Occupations.

Total expenditures by occupation were calculated by taking the OES number of employees multiplied by the OES annual average salary. The wage

and salary expenditures were aggregated based on the groupings in Table 5. We determined the proportion of total wage costs that each subcategory represents.

These proportions listed in Table 5 represent the major rebased and revised home health blended Wage and Salary index weights.

TABLE 5—PROPOSED HOME HEALTH OCCUPATIONAL WAGES AND SALARIES INDEX (WAGES AND SALARIES COMPONENT OF THE PROPOSED 2010 BASED HOME HEALTH MARKET BASKET)

Cost category	2003 Weight	Proposed 2010 weight	Price proxy	BLS Series ID
Health-Related Professional and Technical (P&T).	50.812	33.373	ECI for Wages & Salaries for Civilian Hospital Workers.	CIU10262200 00000I
Non Health-Related P&T	2.253	ECI for Wages & Salaries in Private Industry for Professional, Specialty & Technical Workers.	CIU20254000 00000I
Managerial/Supervisory	9.007	8.260	ECI for Wages & Salaries in Private Industry for Executive, Administrative & Managerial Workers.	CIU20200001 10000I
Administrative/Clerical	7.596	7.720	ECI for Wages & Salaries in Private Industry for Administrative Support, Including Clerical Workers.	CIU20200002 20000I
Health and Social Assistance Services	32.584	35.772	ECI for Wages & Salaries for Civilian Healthcare and Social Assistance.	CIU10262000 00000I
Other Service Occupations	12.622	ECI for Wages & Salaries in Private Industry Service Occupations.	CIU20200003 00000I
Total	100.000	100.000		

A comparison of the yearly changes from CY 2010 to CY 2013 for the 2003-based HH wage and salary blend and the

proposed 2010-based home health wage and salary blend is shown in Table 6. The average annual increase in the two

price proxies is similar, and in no year is the difference greater than 0.3 percentage point.

TABLE 6—ANNUAL GROWTH IN PROPOSED 2010 HH WAGE BLEND AND 2003 HH WAGE BLEND

	2010	2011	2012	2013
HH Wage Blend 2010	1.6	1.5	2.1	2.7

TABLE 6—ANNUAL GROWTH IN PROPOSED 2010 HH WAGE BLEND AND 2003 HH WAGE BLEND—Continued

	2010	2011	2012	2013
HH Wage Blend 2003	1.5	1.5	1.8	2.4

Source: IHS Global Insight, Inc, 2nd Quarter 2012 forecast with historical data through 1st Quarter 2012.

• *Employee benefits:* For measuring employee benefits price growth in the 2010-based home health market basket, we are proposing to apply applicable

price proxies to the six occupational subcategories that are used for the wage blend listed in Table 7. The percentage change in the blended price of home

health employee benefits is applied to this component, which is described in Table 7.

TABLE 7—PROPOSED HOME HEALTH OCCUPATIONAL BENEFITS INDEX (EMPLOYEE BENEFITS COMPONENT OF THE PROPOSED 2010-BASED HOME HEALTH MARKET BASKET)

Cost category	2003 Weight	Proposed 2010 weight	Price proxy
Health-Related Professional and Technical (P&T)	50.506	33.506	ECI for Benefits for Civilian Hospital Workers.
Non Health-Related P&T	2.246	ECI for Benefits in Private Industry for Professional, Specialty & Technical Workers.
Managerial/Supervisory	8.766	8.029	ECI for Benefits in Private Industry for Executive, Administrative & Managerial Workers.
Administrative/Clerical	7.698	7.789	ECI for Benefits in Private Industry for Administrative Support, Including Clerical Workers.
Health and Social Assistance	33.024	35.887	ECI for Benefits for Civilian Healthcare and Social Assistance Workers.
Other Service Occupations	12.542	ECI for Benefits in Private Industry Service Occupations.
Total	100.000	100.000	

There is no available data source that exists for benefit expenditures by occupation for the home health industry. Thus, to construct weights for the home health occupational benefits index we calculated the ratio of benefits to wages and salaries for CY 2010 for the six BLS ECI series we are proposing to use in the blended wage and benefit indexes. To derive the relevant benefit weight, we applied the benefit-to-wage ratios to each of the six occupational

subcategories from the 2010 OES wage and salary weights, and normalized. For example, the ratio of benefits to wages from the 2010 home health occupational wage and benefit indexes for home health managers is 0.976. We apply this ratio to the 2010 OES weight for wages and salaries for home health managers, 8.260, and then normalize those weights relative to the other five benefit occupational categories to obtain a

benefit weight for home health managers of 8.029.

A comparison of the yearly changes from CY 2010 to CY 2013 for the 2003-based HH benefit blend and the proposed 2010-based home health benefit blend is shown in Table 8. The average annual increase in the two price proxies is similar, and in no year is the difference greater than 0.3 percentage point.

TABLE 8—ANNUAL GROWTH IN PROPOSED 2010 HH BENEFITS BLEND AND 2003 HH BENEFITS BLEND

	2010	2011	2012	2013
HH Benefits Blend 2010	2.6	2.7	2.7	2.8
HH Benefits Blend 2003	2.4	3.0	2.5	2.9

Source: IHS Global Insight, Inc, 2nd Quarter 2012 forecast with historical data through 1st Quarter 2012.

• *Administrative and Support:* We are proposing to use the ECI for Compensation for Office and Administrative Support Services (private industry) (BLS series code #CIU2010000220000I) to measure price growth of this cost category. The 2003-based index did not reflect this detailed cost category.

• *Financial Services:* We are proposing to use the ECI for Compensation for Financial Activities (private industry) (BLS series code #CIU201520A000000I) to measure price

growth of this cost category. The 2003-based index did not reflect this detailed cost category.

• *Medical Supplies:* We are proposing to use the PPI for Medical Surgical & Personal Aid Devices (BLS series code #WPU156) to measure price growth of this cost category. The 2003-based index did not reflect this detailed cost category.

• *Rubber and Plastics:* We are proposing to use the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure price growth of

this cost category. The 2003-based index did not reflect this detailed cost category.

• *Operations and Maintenance:* We are proposing to use CPI for Fuel and Utilities (BLS series code #CUUR0000SAH2) to measure price growth of this cost category. The same proxy was used for the 2003-based market basket.

• *Professional Liability Insurance:* We are proposing to use the CMS Physician Professional Liability Insurance price index to measure price growth of this

cost category. The 2003-based index used the CPI for Household Insurance as the price proxy for this component. We are proposing to revise the price proxy for this category as we believe that it is more technically appropriate to proxy PLI price changes by an index specific to medical liability insurance. CMS currently does not have a PLI index specific to the HHA industry so we are proposing to use the CMS Physician Liability Insurance Index as we believe this would reasonably reflect the price changes associated with medical liability insurance purchased by home health agencies.

To accurately reflect the price changes associated with physician PLI, each year, we solicit PLI premium data for physicians from a sample of commercial carriers. This information is not collected through a survey form, but instead is requested directly from, and provided by (on a voluntary basis), several national commercial carriers. As we require for our other price proxies, the PLI price proxy is intended to reflect the pure price change associated with this particular cost category. Thus, it does not include changes in the mix or level of liability coverage. To accomplish this result, we obtain premium information from a sample of commercial carriers for a fixed level of coverage, currently \$1 million per occurrence and a \$3 million annual limit. This information is collected for every State by physician specialty and risk class. Finally, the State-level, physician-specialty data are aggregated by effective premium date to compute a

national total, using counts of physicians by State and specialty as provided in the AMA publication, *Physician Characteristics and Distribution in the U.S.*

- **Telephone:** We are proposing to use CPI for Telephone Services (BLS series code #CUUR0000SEED) to measure price growth of this cost category. The same proxy was used for the 2003-based market basket.

- **Postage:** We are proposing to use CPI for Postage (BLS series code #CUUR0000SEEC01) to measure price growth of this cost category. The same proxy was used for the 2003-based market basket.

- **Professional Fees:** We are proposing to use the ECI for Compensation for Professional and Related Workers (private industry) (BLS series code #CIS2010000120000I) to measure price growth of this category. The same proxy was used for the 2003-based market basket.

- **Other Products:** We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code #) to measure price growth of this category. For the 2003-based market basket we used the CPI for All Items Less Food and Energy to proxy this category. We believe that the PPI better reflects business input costs than the CPI index which better reflects cost faced by consumers.

- **Other Services:** We are proposing to use the ECI for Compensation for Service Occupations (private) (BLS series code #CIU2010000300000I) to measure price growth of this category.

The same proxy was used for the 2003-based market basket.

- **Transportation:** We are proposing to use the CPI for Transportation (BLS series code #CUUR00000SAT) to measure price growth of this category. The 2003-based market basket used the CPI for Private Transportation (BLS series code #CUUS0000SAT1). We are proposing to revise the price proxy to reflect price inflation of both private and public transportation costs. We are proposing this change as further investigation of the MCR instructions request providers to include both private and public transportation costs.

- **Fixed capital:** We are proposing to use the CPI for Owner's Equivalent Rent (BLS series code #CUUS0000SEHC) to measure price growth of this cost category. The same proxy was used for the 2003-based market basket.

- **Movable Capital:** We are proposing to use the PPI for Machinery and Equipment (BLS series code #WPU11) to measure price growth of this cost category. The same proxy was used for the 2003-based market basket.

As we did in the 2003-based home health market basket, we allocated the Contract Services' share of home health agency expenditures among Wages and Salaries, Employee Benefits, A&G and Other Expenses.

d. Rebasing Results

A comparison of the yearly changes from CY 2010 to CY 2013 for the 2003-based home health market basket and the proposed 2010-based home health market basket is shown in Table 9.

TABLE 9—COMPARISON OF THE 2003-BASED HOME HEALTH MARKET BASKET AND THE PROPOSED 2010-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2010–2013

	Home health market basket, 2003-based	Proposed home health market basket, 2010-based	Difference (proposed 2010-based less 2003-based)
Historical: CY 2010	1.7	1.8	0.1
Historical CY 2011	2.0	2.0	0.0
CY 2012	1.9	2.1	0.2
CY 2013	2.3	2.5	0.2
Average Change: 2010–2013	2.0	2.1	0.1

Source: IHS Global Insight, Inc, 2nd Quarter 2012 forecast with historical data through 1st Quarter 2012.

Table 9 shows that the forecasted rate of growth for CY 2013, beginning January 1, 2013, for the proposed rebased and revised home health market basket is 2.5 percent, while the forecasted rate of growth for the current 2003-based home health market basket is 2.3 percent. The higher growth rate for the 2010-based HHA market basket for CY 2013 is attributable to the proposed wage and benefit blended

price proxies, as well as the relatively faster price growth for the A&G cost category. The revised wage and benefit blended index reflects a larger weight associated with health P&T occupations (which is proxied by the ECIs for Hospital Workers) compared to the 2003-based index. The wage and benefit ECIs for hospital workers are currently projected to grow faster than the other ECIs in the blended indexes.

e. Labor-Related Share

In the 2003-based home health market basket the labor-related share was 77.082 percent while the remaining non-labor-related share was 22.918 percent. In the proposed revised and rebased home health market basket, the labor-related share would be 78.535 percent. The labor-related share includes wages and salaries and employee benefits, as well as allocated

contract labor costs. The proposed non-labor-related share would be 21.465 percent. The increase in the labor-related share using the 2010-based HH

market basket is primarily due to the increase in costs associated with contract labor. Table 10 details the components of the labor-related share

for the 2003-based and proposed 2010-based home health market baskets.

TABLE 10—LABOR-RELATED SHARE OF CURRENT AND PROPOSED HOME HEALTH MARKET BASKETS

Cost category	2003-based market basket weight	Proposed 2010-based market basket weight
Wages and Salaries	64.484	66.325
Employee Benefits	12.598	12.210
Total Labor-Related	77.082	78.535
Total Non Labor-Related	22.918	21.465

f. Proposed CY 2013 Market Basket Update for HHAs

For CY 2013, we are proposing to use an estimate of the proposed 2010-based HHA market basket to update payments to HHAs based on the best available data. Consistent with historical practice, we estimate the HHA market basket update for the HHA PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's second quarter 2012 forecast with history through the first quarter of 2012, the projected HHA market basket update for CY 2013 is 2.5 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 2.5 percent for CY 2013. Furthermore, because the proposed CY 2013 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.5 percent), we also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the CY 2013 annual update in the final rule.

2. CY 2013 Home Health Payment Update Percentage

Section 3401(e) of the Affordable Care Act amended section 1895(b)(3)(B) of the Act by adding a new clause (vi) which states, "After determining the home health market basket percentage increase * * * the Secretary shall reduce such percentage * * * for each of 2011, 2012, and 2013, by 1 percentage point. The application of this clause may result in the home health market basket percentage increase under clause (iii) being less than 0.0 for a year, and

may result in payment rates under the system under this subsection for a year being less than such payment rates for the preceding year." Therefore, the proposed CY 2013 market basket update of 2.5 percent must be reduced by 1 percentage point. Thus, the proposed CY 2013 home health payment update is 1.5 percent.

3. Home Health Quality Reporting Program (QRP)

a. 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 HHA that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the HH 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 market basket percentage increase. HHAs that do not meet the reporting requirements are subject to a 2 percentage point reduction to the home health 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 sub clause (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."

As codified at § 484.250(a), we established that the quality reporting requirements could be met by the submission of OASIS assessments and Home Health CAHPS. In the CY 2012 HH PPS final rule (76 FR 68576), we listed selected measures for the HH QRP and also established procedures for making the information available to the public by placing the information on the Home Health Compare Web site. The selected measures that are made available to the public can be viewed on the Home Health Compare Web site located at <http://www.medicare.gov/HHCompare/Home.asp>.

In the CY 2012 HH PPS final rule (76 FR 68575), we finalized that we would also use measures derived from Medicare claims data to measure home health quality.

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

The Home Health 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 five 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 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 failure to comply with the CoPs.

Home Health Agencies do not need to submit OASIS data for those patients who are excluded from the OASIS submission requirements under the Home Health Conditions of Participation (CoPs) § 484.1 through § 484.265. As described in the Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies Final Rule (CMS–3006–F) (70 FR 76202), these are:

- Those patients receiving only nonskilled services;
- Those patients for whom neither Medicare nor Medicaid is paying for home health care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Those patients receiving pre- or post-partum services; or
- Those patients under the age of 18 years.

As set forth in the Medicare Program; Home Health Prospective Payment System Refinement and Rate Update for Calendar Year 2008 Final Rule (CMS–1541–CF) (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, 2012 are not subject to the 2 percentage point reduction to their market basket update for CY 2013. These exclusions only affect quality reporting requirements and do not affect the HHA's reporting responsibilities under the Conditions of Participation and Conditions of Payment (70 FR 76202).

c. Home Health Care Quality Reporting Program Requirements for CY 2014 Payment and Subsequent Years

(1) Submission of OASIS data

For CY 2013, we propose to consider OASIS assessments submitted by HHAs to CMS in compliance with HHA Conditions of Participation and Conditions for Payment for episodes beginning on or after July 1, 2011 and before July 1, 2012 as fulfilling one portion of the quality reporting requirement for CY 2013. This time period would allow for 12 full months of data collection and would provide us with the time necessary to analyze and make any necessary payment adjustments to the payment rates for CY 2013. We propose to continue this

pattern for each subsequent year beyond CY 2013, considering OASIS assessments submitted in the time frame between July 1 of the calendar year two years prior to the calendar year of the Annual Payment Update (APU) effective date and July 1 of the calendar year one year prior to the calendar year of the APU effective date as fulfilling the OASIS portion of the quality reporting requirement for the subsequent APU.

(2) Acute Care Hospitalization Claims-Based Measure

We have determined that claims data are a more robust source of data for accurately measuring acute care hospitalizations than other data sources. We propose that the claims-based Acute Care Hospitalization measure replace the OASIS-based measure on Home Health Compare. The OASIS-based measure will continue to be reported on the agency-specific Certification and Survey Provider Enhanced Reporting system (CASPER) reports.

Due to technical issues with Home Health Compare files, we will delay the reporting of both “Emergency Department Use Without Hospitalization” and “Acute Care Hospitalization” until such time as the technical issues are resolved. The OASIS-based Acute Care Hospitalization measure will continue to be made available to the public via Home Health Compare until it is replaced with the claims-based measure.

To summarize, for the CY 2013 payment update and for subsequent annual payment updates, we propose to continue to use a HHA's submission of OASIS assessments between July 1 and June 30 as fulfilling one portion of the quality reporting requirement for each payment year. Medicare claims data and HHCAHPS data will also be used to measure home health care quality.

d. Home Health Care CAHPS Survey (HHCAHPS)

In the HH PPS Rate Update for CY 2012 HH PPS final rule (76 FR 68577), we stated that the expansion of the home health quality measures reporting requirements for Medicare-certified agencies includes the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care (HHCAHPS) Survey for the CY 2012 annual payment update (APU). In CY 2012 we moved forward with the HHCAHPS linkage to the pay-for-reporting (P4R) requirements affecting the HH PPS rate update for CY 2012. We are maintaining the stated HHCAHPS data requirements for CY 2013 that were set out in the CY 2012 HH PPS final rule, for the continuous monthly data

collection and quarterly data submission of HHCAHPS data.

Background and Description of HHCAHPS

As part of the United States Department of Health and Human Services' (DHHS) Transparency Initiative, we have 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) CAHPS® program, and endorsed by the National Quality Forum (NQF). 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 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 would enable valid comparisons across all home health agencies (HHAs). The history and development process for HHCAHPS has been given in previous rules, but it is also available on our Web site <https://homehealthcahps.org> and also, in the annually-updated *HHCAHPS Protocols and Guidelines Manual*, which is downloadable from <https://homehealthcahps.org>.

For public reporting purposes, we present five measures—three composite measures and two global ratings of care—from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across home health agencies. Each composite measure consists of four or more questions 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 not supposed to measure the aspects of home health clinical care that can be captured through a medical record. Rather, the HHCAHPS survey focuses on areas where the home health patient is the best or only source for the

information. We believe that the HHCAHPS survey is a valid measure of patient's perspectives of home health care. The developmental work for the HHCAHPS survey began in mid-2006, and the first HHCAHPS survey was field-tested (to validate the length and content of the survey) in 2008 by the AHRQ and the CAHPS® grantees, and the final HHCAHPS survey was used in a national randomized mode experiment in 2009 through 2010.

The HHCAHPS survey is currently available in several languages. At the time of the CY 2010 HH PPS final rule, HHCAHPS was only available in English and Spanish translations. In the proposed rule for CY 2010, we stated that we would provide additional translations of the survey over time in response to suggestions for any additional language translations. We now offer HHCAHPS in English, Spanish, Chinese, Russian, and Vietnamese languages. We will continue to consider additional 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 from <https://homehealthcahps.org>. Home health patients are eligible for HHCAHPS if they received at least two skilled home health visits in the past two months, and 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 pulling sample;
- Receive hospice care;
- Received 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
- Requested that their names not be released to anyone.

We stated in previous rules that Medicare-certified agencies are required to contract with an approved HHCAHPS survey vendor. This requirement is also codified. Beginning in summer 2009, interested vendors applied to become approved HHCAHPS survey vendors. 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 now have approximately 40 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at <https://homehealthcahps.org>.

HHCAHPS Oversight Activities

We stated in prior final rules that vendors and HHAs would be 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 HHAs and approved survey vendors follow the *HHCAHPS Protocols and Guidelines Manual*. As stated previously in the CY 2010, CY 2011, and CY 2012 final rules, all 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 should include the following:

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

As part of the oversight activities, the HHCAHPS Survey Coordination Team conducts on-site visits to the approved HHCAHPS survey vendors. The purpose of the site visits is to allow the HHCAHPS Coordination Team to observe the entire Home Health Care CAHPS Survey implementation process, from the sampling stage through file preparation and submission, as well as to assess how the HHCAHPS data are stored. The HHCAHPS Survey Coordination Team reviews the 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 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 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.

We are proposing to codify the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We are proposing to include this survey requirement at § 484.250(c).

HHCAHPS Requirements for CY 2014

For the CY 2014 APU, we propose to continue monthly HHCAHPS data collection and reporting for four quarters. The data collection period for CY 2014 would include second quarter 2012 through first quarter 2013 (the months of April 2012 through March 2013). HHAs would be required to submit their HHCAHPS data files to the Home Health CAHPS Data Center for CY 2014 for the second quarter 2012 by 11:59 p.m., Eastern Time on October 18, 2012; for the third quarter 2012 by 11:59 p.m., Eastern Time on January 17, 2013; for the fourth quarter 2012 by 11:59 p.m., Eastern Time on April 18, 2013; and for the first quarter 2013 by 11:59 p.m., Eastern Time on July 18, 2013.

As noted, we exempt HHAs receiving Medicare certification on or after April 1, 2012 from the full HHCAHPS reporting requirement for the CY 2014 APU, because these HHAs were not Medicare-certified in the period of April 1, 2011 through March 31, 2012. These HHAs would not need to complete a Participation Exemption Request Form for the CY 2014 Annual Payment Update. We propose to maintain this stated exemption for new HHAs.

As noted, HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2011 through March 31, 2012 would be exempt from the HHCAHPS data collection and submission requirements for the CY 2014 APU. Such agencies would be required to submit their patient counts for the period of April 1, 2011 through March 31, 2012 on the Participation Exemption Request form posted at <https://homehealthcahps.org> by 11:59 p.m., Eastern Time on January 17, 2013. This deadline would be firm, as would be all of the quarterly data submission deadlines.

HHCAHPS Requirements for CY 2015

For the CY 2015 APU, we propose to continue to require the continuous

monthly HHCAHPS data collection and reporting for four quarters. The data collection period for CY 2015 would include second quarter 2013 through first quarter 2014 (the months of April 2013 through March 2014). HHAs would be required to submit their HHCAHPS data files to the Home Health CAHPS Data Center for CY 2014 for the second quarter 2013 by 11:59 p.m., Eastern Time on October 17, 2013; for the third quarter 2013 by 11:59 p.m., Eastern Time on January 16, 2014; for the fourth quarter 2013 by 11:59 p.m., Eastern Time on April 17, 2014; and for the first quarter 2014 by 11:59 p.m., Eastern Time on July 17, 2014.

We propose to continue to exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2012 through March 31, 2013) on or after April 1, 2013 from the full HHCAHPS reporting requirement for the CY 2015 APU, because these HHAs would not have been Medicare-certified throughout the period of April 1, 2012 through March 31, 2013. These HHAs do not need to complete a Participation Exemption Request Form for the CY 2015 Annual Payment Update. We propose to maintain this stated exemption for new HHAs.

Likewise, we would require that all HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2012 through March 31, 2013 would be exempt from the HHCAHPS data collection and submission requirements for the CY 2015 APU. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2012 through March 31, 2013 would be required to submit their patient counts on the Participation Exemption Request form for CY 2015 posted at <https://homehealthcahps.org> by 11:59 p.m., Eastern Time on January 16, 2014. This deadline would be firm, as would be all of the quarterly data submission deadlines.

HHCAHPS Reconsiderations and Appeals Process

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

We believe that the reconsiderations process for HHCAHPS should not be burdensome to HHAs. We have modeled

the HHCAHPS reconsiderations process after the one that is used for Hospital CAHPS, in use for nearly 7 years. We have described the HHCAHPS reconsiderations process requirements in the notification memorandum that the RHHIs/MACs sent to the affected HHAs, on behalf of CMS. HHAs have 30 days to send their reconsiderations to CMS. CMS has and will continue to fully examine all HHA reconsiderations.

Summary of Proposed Changes in CY 2013

We are proposing only one change for the CY 2013 rule—to codify the HHCAHPS guideline that HHAs ensure that survey vendors fully comply with all HHCAHPS requirements.

For Further Information on the HHCAHPS Survey

We strongly encourage HHAs to learn about the survey and view the HHCAHPS Survey Web site at the official Web site for the HHCAHPS at <https://homehealthcahps.org>. Home health agencies can also send an email to the HHCAHPS Survey Coordination Team at HHCAHPS@rti.org, or telephone toll-free (1-866-354-0985) for more information about HHCAHPS.

4. Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. For CY 2013, as in previous years, we are proposing to base the wage index adjustment to the labor portion of the HH PPS rates on the most recent pre-floor and pre-reclassified hospital wage index. We would apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence). 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). We have consistently used the pre-floor, pre-reclassified hospital wage index data to adjust the labor portion of the HH PPS rates. We believe the use of the pre-floor, pre-reclassified hospital wage index data results in an appropriate adjustment to the labor portion of the costs, as required by statute.

In the CY 2006 HH PPS final rule (70 FR 68132), we began adopting revised

labor market area definitions as discussed in the Office of Management and Budget (OMB) Bulletin No. 03-04 (June 6, 2003). This bulletin announced revised definitions for Metropolitan Statistical Areas (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 addition, OMB published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. This rule incorporates the CBSA changes published in the most recent OMB bulletin. The OMB bulletins are available at <http://www.whitehouse.gov/omb/bulletins/index.html>.

Finally, we would continue to use the methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there were no IPPS hospitals and, thus, no hospital wage data on which to base the calculation of the HH PPS wage index. For rural areas that do not have IPPS hospitals, and therefore, lack hospital wage data on which to base a wage index, we would use the average wage index from all contiguous CBSAs as a reasonable proxy. For rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005).

For urban areas without IPPS hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2012, the only urban area without IPPS hospital wage data is Hinesville-Fort Stewart, Georgia (CBSA 25980).

The wage index values for rural areas and the CBSAs and their associated wage index values are available via the Internet at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>

5. Proposed CY 2013 Payment Update

a. National Standardized 60-Day Episode Rate

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 rate. As set forth in § 484.220, we adjust the national standardized 60-day episode rate by a case-mix relative weight and a

wage index value based on the site of service for the beneficiary.

In the CY 2008 HH PPS final rule with comment period, we refined the case-mix methodology and also rebased and revised the home health market basket. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage difference, we apply the appropriate wage index value to the labor portion of the HH PPS rates. As discussed in section III.C.1, we have proposed a labor-related share of the case-mix adjusted 60-day episode rate of 78.535 percent and a non-labor-related share of 21.465 percent. The proposed CY 2013 HH PPS rates use the same case-mix methodology and application of the wage index adjustment to the labor portion of the HH PPS rates as set forth in the CY 2008 HH PPS final rule with comment period. 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. The HH PPS regulations at § 484.225 set forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit home health 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 home health

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.

For CY 2013, we propose to update the national per-visit rates for each discipline by the applicable home health payment update percentage of 1.5 percent. We propose to adjust the national per-visit rate by the appropriate wage index based on the site of service for the beneficiary, as set forth in § 484.230. As discussed in the July 3, 2000 HH PPS final rule, for episodes with four or fewer visits, Medicare pays the national per-visit amount by discipline, referred to as a low utilization payment amount (LUPA). We propose to adjust the labor portion of the updated national per-visit rates used to calculate LUPAs by the most recent pre-floor and pre-reclassified hospital wage index. We are also proposing to update the LUPA add-on payment amount and the NRS conversion factor by the applicable home health payment update of 1.5 percent for CY 2013.

Medicare pays the 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 would use to pay the claim.

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

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

b. Proposed Updated CY 2013 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2012 national standardized 60-day episode payment rates, we first look at the CY 2012 rates as a starting point. The CY 2012 national standardized 60-day episode payment rate is \$2,138.52.

Next, we update the payment amount by the proposed CY 2013 home health payment update of 1.5 percent.

As previously discussed in section III.A. ("Case-Mix Measurement") of this proposed rule, our updated analysis of the change in case-mix that is not due to an underlying change in patient health status reveals an additional increase in nominal change in case-mix. Therefore, we propose to reduce rates by 1.32 percent in CY 2013. The national 60-day episode payment amount is adjusted by the case-mix weight of the patient and by the wage index of the geographic area in which the beneficiary is located. The proposed CY 2013 national standardized 60-day episode payment rate for an HHA that submits the required quality data is shown in Table 11. The proposed CY 2013 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the proposed CY 2013 home health payment update (1.5 percent) minus 2 percentage points and is shown in Table 12.

TABLE 11—PROPOSED CY 2013 NATIONAL 60-DAY EPISODE PAYMENT AMOUNT

CY 2012 National standardized 60-day episode payment rate	Multiply by the proposed CY 2013 home health payment update of 1.5 percent	Reduce by 1.32 percent for nominal change in case-mix	Proposed CY 2013 National standardized 60-day episode payment rate
\$2,138.52	× 1.015	× 0.9868	\$2,141.95

TABLE 12—FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA—PROPOSED CY 2013 NATIONAL 60-DAY EPISODE PAYMENT AMOUNT

CY 2012 National standardized 60-day episode payment rate	Multiply by the proposed CY 2013 home health payment update of 1.5 percent minus 2 percentage points (– 0.5 percent)	Reduce by 1.32 percent for nominal change in case-mix	Proposed CY 2013 national standardized 60-day episode payment rate
\$2,138.52	× 0.995	× 0.9868	\$2099.74

c. National Per-Visit Rates

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health 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 Therapy (SLP).

In order to calculate the CY 2013 national per-visit rates, the CY 2012 national per-visit rates for each discipline are updated by the proposed CY 2013 home health payment update of 1.5 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the

beneficiary. The per-visit rates are not case-mix adjusted nor are they subject to the 1.32 percent reduction related to the nominal increase in case-mix.

The per-visit payment amounts for LUPAs are separate from the LUPA Add-On amount which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2013 national per-visit rates are shown in Table 13.

TABLE 13—PROPOSED CY 2013 NATIONAL PER-VISIT PAYMENT AMOUNTS

Home health discipline type	CY 2012 per-visit amounts per 60-day episode	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
		Multiply by the proposed CY 2013 payment update of 1.5 percent	Proposed CY 2013 per-visit payment	Multiply by the proposed CY 2013 payment update of 1.5 percent minus 2 percentage points (– 0.5 percent)	Proposed CY 2013 per-visit payment
HH Aide	\$51.13	× 1.015	\$51.90	× 0.995	\$50.87
MSS	180.96	× 1.015	183.67	× 0.995	180.06
OT	124.26	× 1.015	126.12	× 0.995	123.64
PT	123.43	× 1.015	125.28	× 0.995	122.81
SN	112.88	× 1.015	114.57	× 0.995	112.32
SLP	134.12	× 1.015	136.13	× 0.995	133.45

d. LUPA Add-on Payment Amount Update

Beginning in CY 2008, LUPA episodes that occur as the only episode or initial episode in a sequence of adjacent episodes are adjusted by adding an additional amount to the LUPA payment before adjusting for area wage differences. We update the LUPA

payment amount by the proposed CY 2013 home health payment update of 1.5 percent. The LUPA add-on payment amount is not subject to the 1.32 percent reduction related to the nominal increase in case-mix. For CY 2013, we propose that the add-on to the LUPA payment to HHAs that submit the required quality data be updated by the proposed CY 2013 home health

payment update of 1.5 percent. The proposed CY 2013 LUPA add-on payment amount is shown in Table 14. We propose that the add-on to the LUPA payment to HHAs that do not submit the required quality data would be updated by the proposed CY 2013 home health payment update (1.5 percent) minus two percentage points.

TABLE 14—PROPOSED CY 2013 LUPA ADD-ON AMOUNTS

CY 2012 LUPA add-on amount	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
	Multiply by the proposed CY 2013 payment update of 1.5 percent	Proposed CY 2013 LUPA add-on amount	Multiply by the proposed CY 2013 payment update of 1.5 percent minus 2 percentage points (– 0.5 percent)	Proposed CY 2013 LUPA add-on amount
\$94.62	× 1.015	\$96.04	× 0.995	\$94.15

e. Nonroutine Medical Supply
Conversion Factor Update

Payments for nonroutine medical
supplies (NRS) are computed by

multiplying the relative weight for a
particular severity level by the NRS
conversion factor. We first increase CY
2012 NRS conversion factor (\$53.28) by

the proposed payment update of 1.5
percent. The final updated CY 2013
NRS conversion factor for 2013 appears
in Table 15.

TABLE 15—PROPOSED CY 2013 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2012 NRS conversion factor	Multiply by the proposed CY 2013 payment update of 1.5 percent	Proposed CY 2013 NRS conversion factor
\$53.28	× 1.015	\$54.08

Using the NRS conversion factor
(\$54.08) for CY 2013, the payment

amounts for the various severity levels
are shown in Table 16.

TABLE 16—PROPOSED CY 2013 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative Weight	Proposed CY 2013 NRS payment amount
1	0	0.2698	\$14.59
2	1 to 14 ...	0.9742	52.68
3	15 to 27	2.6712	144.46
4	28 to 48	3.9686	214.62
5	49 to 98	6.1198	330.96
6	99+	10.5254	569.21

For HHAs that do not submit the
required quality data, we again begin
with the CY 2012 NRS conversion
factor. We first increase the CY 2012

NRS conversion factor (\$53.28) by the
proposed CY 2013 home health
payment update of 1.5 percent minus 2
percentage points. The CY 2013 NRS

conversion factor for HHAs that do not
submit quality data is shown in Table
17.

TABLE 17—PROPOSED CY 2013 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2012 NRS Conversion Factor	Multiply by the proposed CY 2013 payment update of 1.5 percent minus 2 percentage points (–0.5 percent)	Proposed CY 2013 NRS conversion factor
\$53.28	× 0.995	\$53.01

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 18.

TABLE 18—PROPOSED CY 2013 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed NRS payment amount
1	0	0.2698	\$14.30
2	1 to 14 ...	0.9742	51.64
3	15 to 27	2.6712	141.60
4	28 to 48	3.9686	210.38
5	49 to 98	6.1198	324.41
6	99+	10.5254	557.95

6. Rural Add-On

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

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for home health 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 home health 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.

The statute 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 home health services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

The 3 percent rural add-on is applied to the national standardized 60-day episode rate, national per-visit rates, LUPA add-on payment, and NRS conversion factor when home health services are provided in rural (non-CBSA) areas. Refer to Tables 19 through 23 for these payment rates.

TABLE 19—PROPOSED CY 2013 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		
Proposed CY 2013 national standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 national standardized 60-day episode payment rate	Proposed CY 2013 national standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 national standardized 60-day episode payment rate
\$2,141.95	× 1.03	\$2,206.21	\$2,099.74	× 1.03	\$2,162.73

TABLE 20—PROPOSED CY 2013 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

Home health discipline type	For HHAs that do submit quality data			For HHAs that do not submit quality data		
	Proposed CY 2013 per-visit rate	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 per-visit rate	Proposed CY 2013 per-visit rate	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 per-visit rate
HH Aide	\$51.90	× 1.03	\$53.46	\$50.87	× 1.03	\$52.40
MSS	183.67	× 1.03	189.18	180.06	× 1.03	185.46
OT	126.12	× 1.03	129.90	123.64	× 1.03	127.35
PT	125.28	× 1.03	129.04	122.81	× 1.03	126.49
SN	114.57	× 1.03	118.01	112.32	× 1.03	115.69
SLP	136.13	× 1.03	140.21	133.45	× 1.03	137.45

TABLE 21—PROPOSED CY 2013 LUPA ADD-ON AMOUNTS FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that do submit quality data			For HHAs that do not submit quality data		
Proposed CY 2013 LUPA add-on amount	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 LUPA add-on amount	Proposed CY 2013 LUPA add-on amount	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 LUPA add-on amount
\$96.04	× 1.03	\$98.92	\$94.15	× 1.03	\$96.97

TABLE 22—PROPOSED CY 2013 NRS CONVERSION FACTOR FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that do submit quality data			For HHAs that do not submit quality data		
Proposed CY 2013 conversion factor	Multiply by the 3 percent rural add-on	Proposed rural CY 2013 conversion factor	Proposed CY 2013 conversion factor	Multiply by the 3 percent rural add-on	Proposed CY rural 2013 conversion factor
\$54.08	× 1.03	\$55.70	\$53.01	× 1.03	\$54.60

TABLE 23—PROPOSED CY 2013 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN RURAL AREAS

Severity level	Points (scoring)	For HHAs that do submit quality data (NRS Conversion Factor = \$55.70)		For HHAs that do not submit quality data (NRS Conversion Factor = \$54.60)	
		Relative weight	Total NRS payment amount for rural areas	Relative weight	Total NRS payment amount for rural areas
1	0	0.2698	\$15.03	0.2698	\$14.73
2	1 to 14	0.9742	54.26	0.9742	53.19
3	15 to 27	2.6712	148.79	2.6712	145.85
4	28 to 48	3.9686	221.05	3.9686	216.69
5	49 to 98	6.1198	340.87	6.1198	334.14
6	99+	10.5254	586.26	10.5254	574.69

D. Home Health Face-to-Face Encounter

1. Acute or Post-Acute Physician Flexibility

As a condition for payment, the Affordable Care Act requires that, prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or an allowed nonphysician practitioner (NPP) has had a face-to-face encounter with the patient. Specifically, the Affordable Care Act states that 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 and inform the certifying physician, who documents the encounter as part of the certification of eligibility. In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs, the physician who cared for the patient in an acute or post-acute care facility, and who had privileges in such facility, could also perform the face-to-face encounter and inform the certifying physician, who would document the encounter as part of the certification of eligibility, and that encounter supported the patient's homebound status and need for skilled services.

For patients admitted to home health following care in an acute or post-acute care facility, the home health industry has asked whether it would be acceptable for an allowed NPP, working in the acute or post-acute facility, to perform the face-to-face encounter in collaboration with the acute or post-acute care physician and communicate his or her clinical findings to the acute or post-acute care physician and, then, for the acute or post-acute care physician to communicate the NPP's

findings to the certifying physician. In practice, it is our understanding from these stakeholders that acute or post-acute care physicians utilize NPPs to obtain information about the patient's clinical condition. As such, the industry suggests that it would be reasonable and appropriate for an allowed NPP working in an acute or post-acute facility to perform the face-to-face encounter and communicate the clinical findings to the acute or post-acute care physician who would then communicate information regarding the patient's homebound status and need for skilled services to the certifying physician. However, we do not believe the statute specifically addresses this situation.

Currently, in guidance in the form of Qs and As and a recent MLN article available on CMS' Home Health Agency Center Web site (<http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>), we have communicated that physician residents, under the supervision of a teaching physician, would be allowed to perform the face-to-face encounter in the acute or post-acute facility and inform the teaching physician of the clinical findings of that face-to-face encounter. The teaching physician, in turn, informs the certifying physician of the clinical findings of the face-to-face encounter, to include the patient's homebound status and the need for skilled services.

A resident is not precluded from performing the face-to-face encounter because he or she is a physician and can perform the encounter. However, we stated that because a resident does not have privileges, the teaching physician would be responsible for informing the certifying physician of the patient's homebound status and need for skilled services. Since we recognize this exchange of information between residents and teaching physicians as allowable under existing face-to-face requirements we believe that NPPs should not be precluded from performing the face-to-face encounter in collaboration with the acute or post-acute care physician who has privileges

and cared for the patient in the acute or post-acute facility, informing the acute or post-acute care physician of the patient's clinical condition, and having the acute or post-acute care physician inform the certifying physician of the patient's homebound status and need for skilled services.

Therefore, for patients admitted to home health from an acute or post-acute facility, we propose to modify the regulations at § 424.22(a)(1)(v) to allow an NPP in an acute or post-acute facility to perform the face-to-face encounter in collaboration with or under the supervision of the physician who has privileges and cared for the patient in the acute or post-acute facility, and allow such physician to inform the certifying physician of the patient's homebound status and need for skilled services. For the specific proposed changes to part 424, see the regulation text of this proposed rule. We encourage stakeholder comment on these proposed changes.

In addition to meeting the goals of the face-to-face encounter provision, we believe this proposed policy change will result in more efficient care coordination between the acute or post-acute NPP and physician, and the certifying physician. We believe this more efficient care delivery will result in an improved transition of care from the acute or post-acute facility to the home health setting. Improving a patient's transition from one healthcare setting to another is widely regarded to be directly related to improved patient care and improved patient outcomes. We believe that this policy change would encourage the acute or post-acute NPP who is best informed of the patient's most current clinical condition to collaboratively communicate the patient's need for home health services to the physician who cared for the patient in the acute or post-acute facility, who would then inform the certifying physician. Because a standard protocol of communication or documentation is not mandated between the acute or post-acute NPP,

the acute or post-acute physician, and a patient's community physician, we believe the additional flexibility with the face-to-face encounter will encourage increased communication between the allowed practitioners and better care coordination for the patient. Further, for patients admitted to home health from an acute or post-acute facility, such a policy would be consistent with what believe is the goal of the provision, which is increased physician involvement in a patient's home health certification, without creating additional burden or preventing access to care. We believe that increased physician and NPP communication regarding the patient's clinical condition fits within the framework of Congress' goals associated with the face-to-face encounter requirement.

2. Regulatory Text Clarification

Additionally, because of the way our regulatory text is constructed at § 424.22(a)(1)(v)(D), we received notice that claims are being denied if the face-to-face documentation is not "clearly titled" by the certifying physician. Our intent was that the face-to-face documentation be clearly titled, but not necessarily by the certifying physician. As such, we propose to revise our regulatory language so as to not be prescriptive as to what entity must title the documentation. The face-to-face documentation must still be signed by the certifying physician, and the content requirements are not changing. For the specific proposed changes to part 424, see the regulation text of this proposed rule. We encourage stakeholder comment on these proposed changes.

E. Therapy Coverage and Reassessments

1. Therapy Coverage

In the CY 2011 HH PPS final rule (75 FR 70389), we clarified policies related to how therapy services are to be provided and documented, and began requiring additional therapy documentation to support medical necessity to address continuing concerns regarding the provision of unnecessary therapy in the home health setting. Specifically, we required that: (1) Measurable treatment goals be described in the plan of care and that the patient's clinical record demonstrate that the method used to assess a patient's function include objective measurement and successive comparisons of measurements, thus enabling objective measurement of progress toward goals and/or therapy effectiveness; (2) a qualified therapist (instead of an assistant) perform the needed therapy service, assess the

patient, measure progress, and document progress toward goals at least once every 30 days during a therapy patient's course of treatment; (3) for those patients needing more than 13 or 19 therapy visits, we require that a qualified therapist (instead of an assistant) perform the therapy service required at the 13th or 19th visit, assess the patient, and measure and document effectiveness of the therapy; and (4) we cease coverage of therapy services if progress towards plan of care goals cannot be measured, unless the documentation supports the expectation that progress can be expected in a reasonable and predictable timeframe. We also finalized policies that provide additional flexibility for the 13th and 19th visit requirements in cases when: (1) The patient resides in a rural area; (2) documented exceptional circumstances prevent the qualified therapist from making the required visit; and (3) patients receive more than one type of therapy.

Although in the CY 2011 HH PPS final rule, we clarified our therapy coverage requirements and instituted policies that, in exceptional circumstances, provide flexibility in fulfilling these requirements, concerns regarding certain aspects of these policies persist. The first issue involves the timing of when the resumption of coverage occurs after a qualified therapist misses one of the required 13th/19th or at least once every 30 days reassessment visits. Currently, when a qualified therapist misses one of the required reassessment visits, once the therapist has completed the required reassessment, coverage resumes after this reassessment visit. Some agencies and therapists believe they are being unfairly penalized by this policy and that the reassessment visit should be covered as therapy was also provided during that visit even though it was not timely.

The second issue concerns patients receiving more than one type of therapy and the lack of coverage for all therapy disciplines if the required reassessment visit is missed for any one of the therapy disciplines for which therapy services are being provided. Currently, if a patient receives more than one type of therapy and the required reassessment visit is missed for any one of the therapy disciplines for which therapy services are being provided, therapy visits are not covered for any of the therapy disciplines until the qualified therapist that missed the reassessment visit complies with the reassessment visit requirements. Therefore, even if qualified therapists from the other therapy disciplines have completed all

their required reassessment visits, therapy visits for these disciplines would not be covered until the qualified therapist who missed the reassessment visit has completed the previously missed reassessment visit. We received feedback from the home health industry that they believe this requirement is unfair in that it denies coverage for therapy disciplines that have met their requirement for qualified therapists to complete a reassessment visit and that they are providing what should be considered covered therapy services. We had additional concerns that this requirement may be negatively impacting beneficiaries' access to therapy services. That is, if an agency anticipates a visit will not be covered because one qualified therapist has not completed the required reassessment, it might be reluctant for any therapy visits to occur until that missed reassessment visit is completed. This is obviously not in the best interest of the beneficiary.

We propose to revise our regulations at § 409.44(c)(2)(i)(E) to state that if a qualified therapist missed a reassessment visit, therapy coverage would resume with the visit during which the qualified therapist completed the late reassessment, not the visit after the therapist completed late reassessment. We would expect minimal changes to claims submissions as a result of this policy change. However, we will monitor claims for unintended consequences, including possible up-coding associated with therapy-related home health resource groups (HHRGs) pre- and post-implementation.

In addition, we propose to revise our regulations at § 409.44(c)(2)(i)(E) to state that in cases where multiple therapy disciplines are involved, if the required reassessment visit was missed for any one of the therapy disciplines for which therapy services were being provided, therapy coverage would cease only for that particular therapy discipline. Therefore, as long as the required therapy reassessments were completed timely for the remaining therapy disciplines, therapy services would continue to be covered for those therapy disciplines. We encourage stakeholder comment on these proposed changes.

2. When Therapy Reassessment Visits Are To Be Conducted

We continue to receive questions regarding acceptable visit ranges for the required 13th and 19th reassessment visits. As we codified at § 409.44(c)(2)(i)(C)(1) and § 409.44(c)(2)(i)(D)(1), if either a patient lives in a rural area, or documented circumstances outside the therapist's

control prevent her or him from completing the reassessment visit at the 13th or 19th visit, this requirement can be met by the therapist having made the visit during the 11th or 12th visit for the required 13th visit or the 17th or 18th visit for the required 19th visit.

We also intended for similar flexibility to be applicable in cases where beneficiaries are receiving more than one type of therapy. Therefore, we included in our regulations at § 409.44(c)(2)(i)(C)(2) and § 409.44(c)(2)(i)(D)(2) that the therapist's visit need only be "close to" the 13th and 19th visits. However, because we recognize the industry's need for additional guidance, to provide more precise guidance, we propose to revise the regulations at § 409.44(c)(2)(i)(C)(1) and § 409.44(c)(2)(i)(D)(1) to clarify that in cases where the patient is receiving more than one type of therapy, qualified therapists could complete their reassessment visits during the 11th, 12th, or 13th visit for the required 13th visit reassessment and the 17th, 18th, or 19th visit for the required 19th visit reassessment. We encourage stakeholder comment on these proposed changes.

3. Technical Correction to G-Code Description

As part of our "Home Health Prospective Payment System Rate Update for Calendar Year 2011," (75 FR 70389) we also provided notice of changes to existing G-codes and new G-codes related to skilled nursing and therapy services (75 FR 43248). In Change Request 7182, we finalized these new and revised G-codes. These codes included G0158, which had as its description, "Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes." After the publication of these codes, a national therapy association informed us that the use of the word, "therapist" rather than "therapy" is technically incorrect for the occupational therapy profession. This association requested that we change the terminology in the G-code. Because this description includes the terminology, "occupational therapist assistant," we propose to make a technical correction to this terminology in G0158, so that the new description would instead include the terminology, "occupational therapy assistant," making it also consistent with § 484.4.

F. Payment Reform: Home Health Study and Report

To address concerns that some beneficiaries are at risk of not having access to Medicare home health services and that the current HH PPS may

encourage providers to adopt selective admission patterns, section 3131(d) of the Affordable Care Act requires the Secretary to conduct a study on home health agency costs involved with providing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness (specifically, beneficiaries with "high levels of severity of illness"). As part of the study, we plan to assess whether these vulnerable populations (low-income Medicare beneficiaries, beneficiaries in medically underserved areas, and beneficiaries with high levels of severity of illness) experience access issues. We may also analyze methods to revise the current HH PPS to ensure access to care and better account for costs for these beneficiaries.

Methods to revise the current HH PPS could include payment adjustments for services that involve either more or fewer resources, changes to reflect resources involved with providing home health services to low-income Medicare beneficiaries or Medicare beneficiaries residing in medically underserved area, and ways outlier payments could be revised to reflect costs of treating Medicare beneficiaries with high severity of illness. In addition, section 3131(d) of the Affordable Care Act allows for the investigation into other issues with the payment system as the Secretary determines appropriate. Therefore, in addition to examining access to care for vulnerable populations and examining ways to more accurately align payment with resource costs, we also plan to evaluate the current HH PPS and develop possible revisions to the payment system that might minimize vulnerabilities.

As we stated in the CY 2012 proposed rule (76 FR 41025), we awarded a contract in the fall of 2010 to perform exploratory work for the study. The contractor performed a literature review of HH PPS payment vulnerabilities and access issues, established and convened technical expert panels and open door forums to help define the vulnerable populations and to gain insight on access issues these populations may face, and performed preliminary analysis looking at resource costs versus Medicare reimbursement. In September 2011, we awarded a study contract to develop an analytic plan, perform detailed analysis, and if necessary, develop recommendations for changes to the HH PPS. We are in the preliminary stages of our analyses. We plan to provide updates regarding our

progress in future rulemaking and open door forums.

The Affordable Care Act requires that the Secretary submit a Report to Congress regarding the study no later than March 1, 2014. The report may contain recommendations for revisions to the HH PPS, recommendations for legislation and administrative action, and recommendations for whether further research is needed. The Congress also provided CMS with the authority to conduct a separate demonstration project to test recommended HH PPS changes resulting from the study.

G. International Classification of Diseases, 10th Edition (ICD-10) Transition Plan and Grouper Enhancements

On April 17, 2012 the Department of Health and Human Services (HHS) published a proposed rule "Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD-10-PCS Medical Data Code Set" (77 FR 22950) that proposed, among other things, to delay, from October 1, 2013 to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10). Any changes to the effective date for ICD-10 implementation would be announced in future rulemaking. We will include an update in our final rule and outline any impact on our ICD-10 transition plans as a result of the proposed change in ICD-10 compliance date.

Although a compliance date change has been proposed, we continue to work with the HH PPS Grouper maintenance contractor to revise the HH PPS Grouper to accommodate ICD-10-CM codes. Home Health Agencies currently report IC-9-CM codes for their patients through OASIS-C. For Medicare patients, the data collection software invokes HH PPS Grouper software. The HH PPS Grouper will be revised to utilize ICD-10-CM codes. If determined to be appropriate, we plan to publish a draft list of ICD-10-CM codes for the HH PPS Grouper by the summer of 2012 for industry review and comment. An email account on the ICD-10 section of the CMS Web site to facilitate receipt of comments on the draft list of ICD-10-CM codes will be provided. Our current plans are to describe the testing approach for the HH PPS Grouper to accommodate and process ICD-10 codes on the ICD-10 section of the CMS Web site in conjunction with the release of the draft grouper in April 2013. We plan

to update providers of any changes to our current plans through the following forums: the ICD–10 Home Health section of the CMS Web site, the Home Health, Hospice and DME Open Door Forums, and provider outreach sessions for ICD–10.

In December 2008, we updated and released Attachment D: Selection and Assignment of OASIS Diagnoses to promote accurate selection and assignment of the patient's diagnosis (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/OASIS_Attachment_D_Guidance.html). This guidance was designed to ensure that providers limited the number of diagnoses assigned to M1024. In addition, Attachment D reminded HHA clinicians/coders to comply with ICD–9–CM coding guidelines when assigning primary and secondary diagnoses to the OASIS items M1020 and M1022. Analysis conducted by our HH PPS Grouper maintenance contractor revealed that many HHAs do not comply with these guidelines. The analysis demonstrated that HHAs are not limiting the number of diagnoses assigned to M1024 and continue to not comply with ICD–9–CM coding guidelines. We have reviewed the diagnosis codes identified in the HH PPS Grouper and confirmed that the only codes that cannot be reported as a primary or secondary diagnosis code (M1020 and M1022) are the fracture codes (V-code). As a result, we are proposing two enhancements for the HH PPS Grouper which we believe will encourage compliance with coding guidelines.

We propose to restrict M1024 to only permit fracture (V-code) diagnoses codes which according to ICD–9–CM coding guidelines cannot be reported in a home health setting as a primary or secondary diagnosis. To further ensure compliance with proper coding guidelines, we propose to pair the fracture codes (V-code) with appropriate diagnosis codes and only when these pairings appear in the primary and payment diagnosis fields will the grouper award points. Currently, when a code from the Diabetes, Skin 1 or Neuro 1 group is submitted in the primary diagnosis position (M1020) the diagnosis code may score additional points. In situations where ICD–9 coding guidelines have required a V-code to be submitted in the M1020 position, HHAs have been instructed to report the etiology code in the payment diagnosis field (M1024) and receive equivalent scoring. Specifically, we are proposing a revision in HHRG logic to permit equivalent scoring when the

Diabetes, Skin 1 or Neuro 1 codes are submitted immediately following the V-code in the M1020 position without requiring utilization of the payment diagnosis field. These grouper enhancements will enforce appropriate use of our payment diagnosis field based upon the guidance issued in Attachment D (putting us in a much more favorable position to eventually retire the payment diagnosis field) until we move to ICD–10 where there is no longer an issue with fracture codes, and ensure ICD–9 and ICD–10 coding guidelines are followed to assist in the eventual transition of grouping the claim, versus OASIS, to determine the appropriate HIPPS code for payment.

IV. Quality Reporting for Hospices

A. Background and Statutory Authority

Section 3004 of the Affordable Care Act amends the Act to authorize a quality reporting program for hospices. As added by section 3004 (c), new section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that fiscal year. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0.0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular FY involved. Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent FYs.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the consensus-based entity which holds a contract regarding performance measurement with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the

Secretary may specify a measure(s) that is(are) not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Under section 1814(i)(5)(D)(iii) of the Act, the Secretary must publish selected measures that will be applicable with respect to FY 2014 no later than October 1, 2012.

B. Public Availability of Data Submitted

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. Such procedures will ensure that a hospice will have the opportunity to review the data regarding the hospice's respective program before it is made public. In addition, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS Web site. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for public reporting of hospice quality data. We also recognize it is essential that the data we make available to the public be meaningful data and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. We will announce the timeline for public reporting of data in future rulemaking.

C. Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2014.

1. Quality Measures Required for Payment Year 2014

In the Hospice Wage Index for Fiscal Year 2012 Final Rule (76 FR 47302, 47320 (August 4, 2011)), to meet the quality reporting requirements for hospices for the FY 2014 payment determination as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

- An NQF-endorsed measure that is related to pain management, NQF #0209: The percentage of patients who report being uncomfortable because of pain on the initial assessment (after admission to hospice services) who report pain was brought to a comfortable

level within 48 hours. The data collection period for this measure is October 1, 2012 through December 31, 2012, and the data submission deadline is April 1, 2013. The data for this measure are collected at the patient level, but are reported in the aggregate for all patients cared for within the reporting period, regardless of payor.

- A structural measure that is not endorsed by NQF: Participation in a Quality Assessment and Performance Improvement (QAPI) program that includes at least three quality indicators related to patient care. Specifically, hospice programs are required to report whether or not they have a QAPI program that addresses at least three indicators related to patient care. In addition hospices are required to check off, from a list of topics, all patient care topics for which they have at least one QAPI indicator. The data collection period for this measure is October 1, 2012 through December 31, 2012, and the data submission deadline is January 31, 2013. Hospices are not asked to report their level of performance on these patient care related indicators. The information being gathered will be used by CMS to ascertain the breadth and content of existing hospice QAPI programs. This stakeholder input will help inform future measure development.

Hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they respond, not on how they respond or on performance level. No additional measures are required for payment year FY 2014.

2. Data Submission Requirements for Payment Year 2014

We will provide a Hospice Data Submission Form to be completed using a web-based data entry site. Training for use of this Web based data submission form will be provided to hospices through webinars and other downloadable materials before the data submission date. Though similar to the data entry site utilized during the hospice voluntary reporting period, the site will be changed to accommodate the addition of the NQF #0209 measure, as well as to simplify the data entry requirements for the structural measure. Hospices will be asked to provide identifying information, and then complete the web based data entry for the required measures. For hospices that cannot complete the web based data entry, a downloadable data entry form will be available upon request.

The data submission form as well as details regarding education and resources related to the data collection

and data submission for both the NQF #0209 measure and the structural measure will be provided on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/>.

D. Quality Measures for Hospice Quality Reporting Program for Payment Year FY 2015 and Beyond

1. Quality Measures Required for Payment Year FY 2015 and Subsequent Years

To meet the quality reporting requirements for hospices for the FY 2015 payment determination and each subsequent year, as set forth in section 1814(i)(5) of the Act, we propose that hospices report the following:

- The NQF-endorsed measure that is related to pain management, NQF #0209: The percentage of patients who report being uncomfortable because of pain on the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours.

- The structural measure: Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care. Specifically, hospice programs would report whether or not they have a QAPI program that addresses at least three indicators related to patient care.

We are not extending the requirement that hospices provide a list of their patient care indicators. We invite comment on the proposed selection of measures.

2. Data Submission Requirements for Payment Year FY 2015.

As previously noted, in the Hospice Wage Index for Fiscal Year 2012 Final Rule, we finalized the following:

- All hospice quality reporting periods subsequent to that for Payment Year FY 2014 be based on a calendar year rather than a calendar quarter. For example, January 1, 2013 through December 31, 2013 will be the data collection period used for determination of the hospice market basket update for each hospice in FY 2015, etc.; and

- Hospices submit data in the fiscal year prior to the payment determination. For FY 2015 and beyond, the data submission deadline will be April 1 of each year. For example, April 1, 2014 will be the data submission deadline used for determination of the hospice market basket update for each hospice in FY 2015, etc.

E. Additional Measures Under Consideration and Standardization of Data Collection

While initially we will build a foundation for quality reporting by requiring hospices to report one NQF-endorsed measure and one structural measure, we seek to achieve a comprehensive set of quality measures to be available for widespread use for quality improvement and also informed decision making. The provision of quality care to hospice patients and families is of utmost importance to CMS. For annual payment determinations beyond FY2015, we are considering an expansion of the required measures to include some additional measures endorsed by NQF. The measures of particular interest are NQF numbers 1634, 1637, 1638, 1639, and 0208 and can be found by searching the NQF site at www.qualityforum.org. We welcome comments on whether all, some, any, or none of these measures should be considered for future rulemaking. A potential timeline and titles of future measures under consideration are included below.

To support the standardized collection and calculation of quality measures specifically focused on hospice services, we believe the required data elements would potentially require a standardized assessment instrument. We are committed to developing a quality reporting program for hospices that utilizes standardized methods to collect data needed to calculate endorsed quality measures. To achieve this goal, we have been working on the initial development and testing of a hospice patient-level data item set. This patient level item set could be used by all hospices at some point in the future to collect and submit standardized data items about each patient admitted to hospice. These data could be used for calculating quality measures. Many of the items currently in testing are already standardized and included in assessments used by a variety of other providers. Other items have been developed specifically for the hospice care settings, and obtain information needed to calculate the hospice-appropriate quality measures that were endorsed by NQF in February 2012. We are considering a target date for implementation of a standardized hospice data item set as early as CY 2014, dependent on development and infrastructure logistics. We welcome comments on the potential implementation of a hospice patient-level data item set in CY 2014.

In developing the standardized data item set, we have included data items that will support the following endorsed measures:

- 1617 Patients Treated With an Opioid Who Are Given a Bowel Regimen

- 1634 Pain Screening
- 1637 Pain Assessment
- 1638 Dyspnea Treatment
- 1639 Dyspnea Screening

Starting with data collection in 2015, we envision these measures as possible measures that we would implement

subject to future rulemaking. We welcome comments on the potential future implementation of these measures and the associated projected timeframe for implementation.

We are also considering future implementation of measures based on an experience of care survey such as the Family Evaluation of Hospice Care Survey (FEHC). The NQF endorsed measure # 0208 Family Evaluation of Hospice Care is such a measure. Implementation of an experience of care

measure and the associated use of a specified survey could precede or follow the implementation of a standardized data set. We do not envision implementation of both a data set and an experience of care survey in the same year and would project implementation in succession in order to avoid excessive burden to hospices. We solicit comment on the succession of implementation of these two potential requirements.

Summary Tables:

Data collection	Data submission	APU impact	Measures
Proposed in This Proposed Rule			
1/1/2013–12/31/2013	4/1/2014	FY 2015 (10/1/2014)	Structural measure without QAPI list NQF 0209.
1/1/2014–12/31/2014	4/1/2015	FY 2016 (10/1/2015)	Structural measure without QAPI list NQF 0209.
Target Date for Potential Future Implementation of Standardized Data Set			
Considering Hospice Standardized Data Item Set for implementation in CY 2014.			
Target Dates for Potential Implementation of Future Measures Under Consideration			
1/1/2015–12/31/2015	4/1/2016	FY 2017 (10/1/2016)	Structural measure without QAPI list NQF 0209.
.....			Considering NQF endorsed measures supported by a standardized data set:
.....			• 1617 Patients Treated With an Opioid Who Are Given a Bowel Regimen
.....			• 1634 Pain Screening
.....			• 1637 Pain Assessment
.....			• 1638 Dyspnea Treatment
.....			• 1639 Dyspnea Screening
.....			Considering NQF endorsed measure derived from the FEHC survey:
.....			• 0208 Family Evaluation of Hospice Care

V. Survey and Enforcement Requirements for Home Health Agencies

A. Background and Statutory Authority

In the 1980s and 1990s, home health services became a rapidly growing segment of Medicare expenditures. During that time, Congress enacted several laws that dramatically expanded the authority of CMS in its administration of the home health benefit. The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–203, enacted on December 22, 1987) amended the Act to incorporate provisions that would create mechanisms to improve the quality of home health services as well as long-term care services. It also provided the Secretary with the authority to change the manner in which CMS regulated and carried out enforcement actions with respect to HHAs participating in the Medicare program. Changes in both the HHA and long-term care arenas required

significant adjustments and increased workload for CMS in its operation and regulatory oversight of these programs.

The OBRA '87 amendments mandated an outcome-oriented survey process for HHAs that would include “a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care,” as reflected in section 1891(c)(2)(C)(i)(II) of the Act. We responded to that mandate by creating an outcome-oriented survey process for HHAs that included specific procedures to be followed, including visits to patients in their homes. We also defined in our policies, although not in regulation, the different types of surveys to be used, including the standard, partial extended and extended surveys addressed in section 1891 of the Act. This proposed rule would codify these types of surveys in regulation.

To participate as an HHA in the Medicare program, an agency or organization must meet the definition of

an HHA in section 1861(o) of the Act. Section 1861(o) of the Act defines an HHA as a public agency or private organization or a subdivision of such an agency or organization, which among other things, is primarily engaged in the provision of skilled nursing services and other therapeutic services, has policies established by a group of professional personnel, maintains clinical records, is licensed under State or local law, and meets the health and safety standards established by the Secretary. Additionally, section 1891(a) of the Act sets out specific participation requirements for HHAs. The regulations implementing sections 1861(o) and 1891(a) of the Act are known as health and safety standards, or CoPs, for HHAs and are codified in 42 CFR part 484.

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. Section 1861(m) of the Act defines the

term “home health services” as services that must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, must be provided on a visiting basis to the individual’s home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies, other than drugs and biologicals, but including osteoporosis drugs.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

The HHA CoPs were originally issued in 1973, with revisions made in 1989 and 1991, to implement provisions of section 4021 of OBRA ‘87, which added section 1891(a) to the Act. Additional minor revisions to the CoPs have been made since that time. Over the years, additional home-health-specific areas of focus for CMS have included adjustments to the home health Prospective Payment System (HH PPS) and Outcome and Assessment Information Set (OASIS).

The CoPs apply to an HHA as an entity, as well as to the services furnished to each individual under the care of the HHA, unless the CoPs are specifically limited to Medicare/Medicaid beneficiaries, such as the OASIS requirements at § 484.11, § 484.20 and § 484.55. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of public monies.

The Secretary is authorized to enter into an agreement with a State survey agency (SA) under section 1864(a) of the Act or a national accreditation organization (AO) under section 1865(a) of the Act, with oversight by CMS Regional Offices, to determine whether HHAs meet the Federal participation requirements for Medicare. Section 1902(a)(33)(B) of the Act provides for SAs to perform the same survey tasks for facilities participating or seeking to participate in the Medicaid program. The results of Medicare and Medicaid-

related surveys are used by CMS and the Medicaid State Agency, respectively, as the basis for a decision to enter into, deny, or terminate a provider agreement with the agency. To assess compliance with Federal participation requirements, surveyors conduct onsite inspections (surveys) of agencies. In the survey process, surveyors directly observe the actual provision of care and services to patients and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual patients. An SA periodically surveys HHAs and certifies its findings to CMS and to the State Medicaid Agency if the HHA is seeking to acquire or maintain Medicare or Medicaid certification, respectively. The general requirements regarding the survey and certification process are codified at 42 CFR part 488 and specific survey instructions are detailed in our State Operations Manual (SOM) (IOM Pub. 100–07) and in policy transmittals. Certain providers and suppliers, including HHAs, are also deemed by CMS to meet the Federal requirements for participation if they are accredited by an AO whose program is approved by CMS to meet or exceed Federal requirements under section 1865(a). However, these deemed providers and suppliers are subject to validation surveys under § 488.7.

On August 2, 1991, we published the Survey Requirements and Alternative Sanctions for Home Health Agencies proposed rule (56 FR 37054) that proposed to establish survey and enforcement requirements, as well as alternative sanctions for HHAs under section 1891 of the Act, implementing the OBRA ‘87 provisions.

While we attempted to finalize the proposed rule numerous times since its publication on August 2, 1991, sweeping changes in the law and other regulations, together with the demands of additional improvement efforts, impeded the promulgation of a final rule. Indeed, in response to the August 2008 Office of Inspector General (OIG) Report, “Deficiency History and Recertification of Medicare Home Health Agencies,” (OEI–09–06–00040), we noted that the August 2, 1991 proposed rule would require substantial revisions and republication to implement the alternative sanctions. Due to the considerable length of time that has passed since publication of the August 2, 1991 proposed rule, we are now publishing a new proposed rule, which would implement those survey and enforcement requirements, as well as establish alternative sanctions specified under 1891(f) for HHAs.

B. Provisions of the Proposed Rule

1. Overview

Sections 4022 and 4023 of OBRA ‘87 amended the Act by adding sections 1891(c) through (f) to establish requirements for surveying and certifying HHAs as well as to establish the authority of the Secretary to utilize varying enforcement mechanisms to terminate participation and to impose alternative sanctions if HHAs were found out of compliance with the CoPs. We propose to add new subparts I and J to 42 CFR part 488 to implement these sections of the Act. New subpart I would provide survey and certification guidance while new subpart J would outline the basis for enforcement of compliance standards for HHAs that are not in substantial compliance with Medicare participation requirements.

In addition, we propose to amend certain sections of 42 CFR part 488, subpart A—General Provisions. Currently, the general provisions include specific references to survey, certification and enforcement procedures for long term care facilities and the residents of those facilities. We are proposing to amend several regulations, where appropriate, to also include reference to HHAs and the patients they serve.

Specifically, we propose to amend § 488.2 to include the statutory reference to home health services (section 1861(m) of the Act), HHAs (section 1861(o) of the Act), and the Conditions of Participation (CoPs) for HHAs and home health quality (section 1891 of the Act).

We propose to amend § 488.3 by revising paragraph (a)(1) to include the statutory citations concerning HHAs mentioned above. In addition, we propose to amend § 488.26 by revising paragraph (c)(2) and (e) to include references to “patient” and “patients” which is how individuals receiving services in an HHA are referenced. Furthermore, we propose to revise the heading for § 488.28 to include reference to HHAs with deficiencies.

Rules for certification, documentation of findings, periodic review of compliance and approval, certification of noncompliance, and determining compliance are set forth, respectively, in §§ 488.12, 488.18, 488.20, 488.24, and 488.26 of this part.

2. Proposed New Subpart I—Survey and Certification of HHAs

a. Basis and Scope (§ 488.700)

Proposed section 488.700 of subpart I would specify the statutory authority for and general scope of standards proposed

in part 488 that establish the requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation. In general, this proposed rule is based on the rulemaking authority in section 1891 of the Act as well as specific statutory provisions identified in the preamble where appropriate.

b. Definitions (§ 488.705)

We propose to add § 488.705 which would define certain terms. Sections 1891(c)(1) and (2) of the Act specify the requirements for types and frequency of surveys to be performed in HHAs, utilizing the terms “standard”, “abbreviated standard”, “extended”, “partial extended” and “complaint” surveys, as well as specifying the minimum components of the standard and extended surveys. Therefore, we are proposing definitions for these surveys at § 488.705.

In addition to those terms, we are proposing to add definitions for “condition-level deficiency,” “deficiency,” “noncompliance,” “standard-level deficiency,” “substandard care,” and “substantial compliance.” The definitions of the different surveys as well as the additional proposed definitions have been a part of longstanding CMS policy, but have not yet been codified in the regulations for HHAs.

c. Standard Surveys (§ 488.710)

At proposed § 488.710, a standard survey would be conducted not later than 36 months after the date of the previous standard survey, as specified at section 1891(c)(2)(A) of the Act. Section 1891(c)(2)(C) of the Act requires for standard surveys, to the extent practicable, to review a case-mix stratified sample of individuals to whom the HHA furnishes services, which is reflected in proposed § 488.710(a)(1). The statute specifies that CMS actually visit the homes of sampled patients, and that CMS conduct a survey of the quality of services being provided (as measured by indicators of medical, nursing, and rehabilitative care). At proposed § 488.710(a), we would specify minimum requirements and provide that visits to homes of patients could be done only with the consent of the patient, their guardian or legal representative. The purpose of the home visit would be to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of each patient as reflected in the patient’s written plan of care and clinical records. Other forms of communication with patients, such as

through telephone calls, could be used to complete surveys, if determined necessary by the State Survey Agency or CMS Regional Office. We also would provide in proposed § 488.710(b) that the survey agency’s failure to follow its own survey procedures would not invalidate otherwise legitimate determinations that deficiencies existed in an HHA. For example, if the Statement of Deficiencies was not forwarded to the provider within 10 days of the end of the exit conference, this would not invalidate the underlying determinations.

d. Partial Extended Survey (§ 488.715)

In proposed § 488.715, the partial extended survey would be conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. It would be conducted when a standard-level noncompliance was identified; or if the surveyor believed that a deficient practice existed at a standard or condition-level that was not examined during the standard survey. During the partial extended survey, the surveyor would review, at a minimum, additional standard(s) under the same CoP in which the deficient practice was identified during the standard survey. The surveyors could also review any additional standards under the same or related CoPs which would assist in making a compliance decision. Under § 488.24 of our regulations, which applies to most other providers and suppliers and upon which this proposed provision is modeled, the SA certifies that a provider is not in compliance with the CoPs where the deficiencies are of such character as to substantially limit the provider’s capacity to furnish adequate care or which adversely affect the health and safety of patients. A CoP may be considered out of compliance (and thus condition-level) for one or more standard level deficiencies, if, in a surveyor’s judgment, the standard level deficiency constitutes a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes. Surveyors are to use their professional judgment, in concert with the Federal forms, policies and interpretive guidelines in their assessment of a provider’s compliance with the CoPs. The same procedures would be used with respect to HHAs.

e. Extended Surveys (§ 488.720)

As described in proposed § 488.720, the extended survey would review compliance with all CoPs and standards applicable to the HHA. It could be conducted at any time, at the discretion of CMS or the SA, but would be

conducted when any condition level deficiency was found. This survey also would review the HHA’s policies, procedures, and practices that produced the substandard care, which we define in proposed § 488.705 as noncompliance with one or more Conditions of Participation at the condition-level. The extended survey would be conducted no later than 14 calendar days after the completion of a standard survey which found the HHA had furnished substandard care. Additionally, the survey would review any associated activities that might have contributed to the deficient practice.

f. Unannounced Surveys (§ 488.725)

Section 1891(c)(1) of the Act requires that standard surveys be unannounced. Moreover, CMS policy (State Operations Manual (SOM) section 2700A) requires that all HHA surveys be unannounced; this policy would be set out at proposed § 488.725, which also would provide that surveys be conducted with procedures and scheduling that renders the onsite surveys as unpredictable in their timing as possible. In addition, section 1891(c)(1) of the Act requires CMS to review State scheduling and survey procedures to ensure that the agency has taken all reasonable steps to avoid giving advance notice to HHAs of impending surveys through these procedures. Generally, as with respect to other provider-types, State survey agencies make every effort to lessen the predictability of a survey occurring at a specific time, day, or month. Moreover, section 1891(c)(1) of the Act states that any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey is subject to a civil money penalty (CMP) not to exceed \$2,000. Accordingly, our proposed regulations at § 488.725 would reflect these survey requirements.

g. Survey Frequency and Content (§ 488.730)

In proposed § 488.730, we would set out the requirements for survey frequency and the substantive content of the survey, as discussed in § 488.710, § 488.715, and § 488.720. Section 1891(c)(2) of the Act requires HHAs to be subject to a standard survey at least every 36 months and the frequency of a standard survey to be commensurate with the need to assure the delivery of quality home health services. This 36 month interval is based upon the last day of the last standard survey. This section of the Act also gives CMS the authority to conduct a survey as often as necessary to assure the delivery of quality home health services by determining whether an HHA complies

with the CoP or to confirm the correction of previous deficiencies. A standard survey or abbreviated standard survey may be conducted within two months of a change in ownership, administration or management of an HHA, as specified in 1891(c)(2)(B)(ii) of the Act, and must be conducted within 2 months of a significant number of complaints reported against the HHA (as determined by CMS), and would also be conducted as otherwise directed by CMS to determine compliance with the CoP, such as the investigation of a complaint. Extended surveys and partial extended surveys may also be conducted at any time. As required in section 1891(c)(2)(D) of the Act, extended surveys and partial extended surveys must be conducted when an HHA is found to have furnished substandard care, and may also be conducted for other reasons at the discretion of CMS or the State in order to determine compliance with the CoP.

h. Surveyor Qualifications (§ 488.735)

Section 1891(c)(2)(C)(iii) of the Act requires “an individual who meets the minimum qualifications established by the Secretary” to conduct a survey of an HHA. We interpret this statutory language to mean that each individual on a survey team must meet certain minimum CMS qualifications. We set forth our proposed criteria for surveyor minimum qualifications in § 488.735. We are proposing that he or she successfully complete the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites prior to conducting an HHA survey.

Proposed § 488.735 would also set out the circumstances that would disqualify a surveyor from surveying a particular HHA as required by section 1891(c)(2)(C)(iii) of the Act. A surveyor would be prohibited from surveying an HHA if the surveyor currently serves, or within the previous two years has served, on the staff of or as a consultant to, the HHA undergoing the survey. Specifically, the surveyor could not have been a direct employee, employment agency staff at the HHA, or an officer, consultant or agent for the surveyed HHA regarding compliance with CoPs. A surveyor would be prohibited from surveying an HHA if he or she has a financial interest or an ownership interest in that HHA. The surveyor would also be disqualified if he or she has a family member who has a financial interest or ownership interest with the HHA to be surveyed or has a family member who is a patient of the HHA to be surveyed.

i. Certification of Compliance or Non-Compliance (§ 488.740)

We propose in § 488.740 to cross reference the rules for certification, documentation of findings, periodic review of compliance and approval, certification of non-compliance, and determining compliance for HHAs as set forth, respectively at § 488.12, § 488.18, § 488.24 and § 488.26 of this part. These general rules must be followed when a State Agency certifies compliance or non-compliance of the HHA with the Act and Conditions of Participation.

j. Informal Dispute Resolution (IDR) (§ 488.745)

We propose in § 488.745 to make available to HHAs an IDR process to address disputes related to condition-level survey findings following an HHA's receipt of the official statement of deficiencies. We propose adding an IDR process that would provide HHAs an informal opportunity to resolve disputes in the survey findings for those HHAs that are seeking recertification from the SA for continued participation in Medicare and for those HHAs that are currently under SA monitoring (either through a complaint or validation survey). Whenever possible, we want to provide every opportunity to settle disagreements at the earliest stage, prior to a formal hearing, conserving time and money potentially spent by the HHA, the State agency, and CMS. The goal of IDR is to offer an HHA the opportunity to refute one or more condition-level deficiencies cited on the official Statement of Deficiencies. An IDR between an HHA and the SA or RO, as appropriate, would allow the HHA an opportunity to provide an explanation of any material submitted to the SA and respond to the reviewer's questions.

In proposed § 488.745, we would provide HHAs with the option to dispute condition-level survey findings or repeat deficiencies warranting a sanction upon their receipt of the official Statement of Deficiencies. When survey findings indicate a condition level deficiency (or deficiencies), CMS or the State, as appropriate, would notify the HHA in writing of its opportunity to request an IDR of those deficiencies. This notice would be provided to the HHA at the time the Statement of Deficiencies is issued to the HHA. The HHA's request for IDR must be submitted in writing, should include the specific deficiencies that are disputed, and should be submitted within the same 10 calendar day period that the HHA has for submitting an acceptable plan of correction.

An HHA's initiation of the IDR process would not postpone or otherwise delay the effective date of any enforcement action. The failure to complete an IDR would not delay the effective date of any enforcement action. Further, if any findings are revised or removed based on IDR, the official Statement of Deficiencies is revised accordingly and any enforcement actions imposed solely as a result of those revised or removed deficiencies are adjusted accordingly. We believe that the IDR procedures would maintain the balance between an HHA's due process concerns and the public's interest in the timely correction of HHA deficiencies.

3. Proposed Subpart J—Alternative Sanctions for Home Health Agencies With Deficiencies

a. Statutory Basis (§ 488.800)

We are proposing rules for enforcement actions for HHAs with deficiencies, including alternative sanctions, at new subpart J. Under sections 1866(b)(2)(B) and 1891(e) of the Act and § 489.53(a)(3), we may terminate an HHA's provider agreement if that HHA is not in substantial compliance with the Medicare requirements (that is, the failure to meet one or more conditions of participation is considered a lack of substantial compliance). We may also terminate an HHA that fails to correct its deficiencies within a reasonable time (ordinarily no more than 60 days), even if those deficiencies are at the standard (rather than condition) level at § 488.28. Prior to OBRA '87, the only action available to CMS to address HHAs out of compliance with Federal requirements was termination of their Medicare provider agreement. Section 4023 of OBRA '87 added subsections 1891(e) and (f) to the Act, which expanded the Secretary's options to enforce Federal requirements for HHAs. Under section 1891(e)(1) of the Act, if the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this title is no longer in compliance with the requirements specified in or pursuant to section 1861(o) or section 1891(a) of the Act and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in section 1891(f)(2)(A)(iii) or terminate the certification of the agency,

and may provide, in addition, for one or more of the other sanctions described in section 1891(f)(2)(A).

We are proposing to set out the statutory basis for the new subsection at proposed § 488.800, which is sections 1891(e) and (f) of the Act. Section 1891(e) provides for termination of home health agencies that fail to comply with Conditions of Participation. This section also provides for ensuring that the procedures with respect to the conditions under which each of the alternative sanctions developed by the Secretary shall be designed to minimize the time between identification of deficiencies and imposition of these sanctions, including imposition of incrementally more severe fines for repeated or uncorrected deficiencies. Furthermore, this section specifies that these sanctions are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

b. Definitions (§ 488.805)

We are proposing to add § 488.805 to define the frequently used terms, including “directed plan of correction,” “immediate jeopardy,” “new admission,” “per instance,” “plan of correction,” “repeat deficiency” and “temporary management”.

Although section 1891 of the Act uses the term “intermediate sanctions,” for consistency with other enforcement rules, this proposed rule uses “alternative sanctions,” which we consider to have the same meaning.

c. General Provisions (§ 488.810)

We propose in § 488.810 general rules for enforcement actions against an HHA with condition-level deficiencies. Sections 1891(e)(1) and (2) of the Act provide that if CMS finds that an HHA is not in compliance with the Medicare home health CoPs 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. Therefore, our decision to impose one or more sanctions, including termination, would be based on condition-level deficiencies, found in an HHA during a survey, pursuant to section 1891(e)(2) of the Act. We would be able to impose one or more sanctions for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

It is also important to note that HHAs acquire certification for participation in

Medicare via a SA survey or via accreditation by a CMS-approved AO. Accreditation by a CMS-approved AO is voluntary and not necessary to participate in Medicare. The AO communicates any condition level findings to the applicable CMS Regional Office. When an accredited HHA is to lose its accreditation status from the AO due to condition-level findings that remain uncorrected, we would follow the usual procedures for the resumption of oversight by the SA and the same procedures for imposition of alternative sanctions if appropriate. Once a sanction was imposed on an HHA, oversight and enforcement of that HHA would be by the SA from the accrediting organization until the HHA achieved compliance and the alternative sanction was removed or until the HHA was terminated from the Medicare program.

It is CMS policy that any deficiencies found at a branch of the HHA would be counted against the HHA as a business entity. Therefore, regardless of whether the deficient practice is identified at the branch or the parent location, all sanctions imposed would apply to the parent HHA. However, these sanctions would not apply to any non-branch subunit that was associated with an HHA if such subunit were independently required to meet the CoPs for HHAs. Such subunit instead could have sanctions imposed on it based on deficient practices found at that subunit. For HHAs that operate branch offices in multiple states, we would base enforcement decisions on surveys conducted by the State in which the parent office is located.

In proposed § 488.810(e) an HHA would be required to submit an acceptable plan of correction (POC) to CMS. We define plan of correction in proposed § 488.805 whether it has standard-level or condition-level as a plan developed by the HHA and approved by CMS that is the HHA’s written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected. More specifically, a POC would detail how an HHA has or would correct each deficiency, how the HHA would act to protect patients in similar situations, how the HHA would ensure that each deficiency did not recur, how the HHA would monitor performance to sustain solutions, and in what timeframe corrective actions would be taken. We would determine if the POC was acceptable based on the information presented in the POC.

In proposed § 488.810(f) CMS would provide written notification of the intent to impose a sanction including the

specific sanction, the statutory basis for the sanction and appeal rights including an opportunity to participate in the proposed Informal Dispute Resolution process.

An HHA may appeal the determination of noncompliance leading to the imposition of a sanction under the provisions of 42 CFR Part 498. A pending hearing does not delay the effective date of a sanction against an HHA and sanctions continue to be in effect regardless of any pending appeals proceedings. Civil money penalties continue to accrue during the pendency of an appeal, but will not be collected until a final agency determination, as we note in proposed § 488.845(f).

d. Factors To Be Considered in Selecting Sanctions (§ 488.815)

Section 1891(e)(2) of the Act provides that if CMS finds that an HHA is not in compliance with the Medicare home health CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, CMS may terminate the provider agreement, impose an alternative sanction(s), or both, at CMS’s discretion for a period not to exceed six months. The choice of any alternative sanction or termination would reflect the impact on patient care and the seriousness of the HHA’s patterns of noncompliance and would be based on the factors proposed in § 488.815. We could propose termination of the provider agreement and apply one or more sanctions for HHAs with the most egregious deficiencies, for an HHA that was unwilling or unable to achieve compliance within a maximum of six months, whether or not the violations constituted an “immediate jeopardy” situation.

In proposed § 488.815 and consistent with section 1891(f)(3) of the Act, procedures for selecting the appropriate alternative sanction, including the amount of any CMP and the severity of each sanction, have been designed to minimize the time between the identification of deficiencies and the final imposition of sanctions. To determine which sanction or sanctions to apply, we propose that we would consider the following:

- Whether the deficiencies pose immediate jeopardy to patient health and safety;
- The nature, incidence, degree, manner, and duration of the deficiencies or noncompliance;
- The presence of repeat deficiencies, the HHA’s compliance history in general, and specifically with reference to the cited deficiencies, and any history

of repeat deficiencies at either the parent or branch location;

- Whether the deficiencies are directly related to a failure to provide quality patient care;
- Whether the HHA is part of a larger organization with documented performance problems;
- Whether the deficiencies indicate a system wide failure of providing quality care.

Section 1891(f)(3) of the Act provides for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. We would define “repeat deficiency” in § 488.805 as a standard or condition-level deficiency that was cited on a survey that was substantially the same as, or similar to, a finding of noncompliance issued within the preceding 365 days. The standard-level findings would be evaluated for condition-level noncompliance based on the HHA’s failure to correct and sustain compliance. As noted in proposed 488.815(c), CMS would consider the presence of repeat deficiencies as a factor in selecting sanctions and civil money penalties.

e. Available Sanctions (§ 488.820)

Section 1891(f)(1)(A) of the Act provides that CMS shall “develop a range of intermediate [or alternative] sanctions” that may be imposed in addition to, or instead of, termination when CMS finds that an HHA has deficiencies. The Act explicitly provides for the following: Civil money penalties, suspension of payment for new admissions, and temporary management. We are proposing those alternative sanctions in this proposed rule. In addition to those specified in the statute, we are proposing to add the following additional alternative sanctions: A directed plan of correction, directed in-service training, and/or suspension of payment for new PPS episodes. The list of alternative sanctions that could be imposed for a noncompliant HHA is in proposed § 488.820.

f. Actions When Deficiencies Pose Immediate Jeopardy (§ 488.825)

Under paragraph 1891(e)(1) of the Act, if CMS determined that the HHA’s deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the HHA of the immediate jeopardy situation and the HHA must correct the deficiencies. We are proposing to implement the statutory requirement by proposing that if the IJ situation was not addressed and resolved within 23 days because the HHA was unable or

unwilling to correct the deficiencies, CMS would terminate the HHA’s provider agreement, using the procedures set out at § 489.53(d). In addition, CMS could impose one or more other alternative sanctions permitted by section 1891(f)(2) of the Act, including a civil money penalty (CMP), temporary management and/or suspension of all Medicare payments before the effective date of termination. We propose to set out these provisions as new § 488.825.

We also propose in § 488.825 that for immediate jeopardy situations, we would terminate the HHA and we would give notice of the termination within 2 days before the effective date of the termination, which is consistent with the requirement for skilled nursing facilities in § 489.53(d)(2)(ii). Under our regular survey process, providers are advised of any immediate jeopardy findings upon discovery of the immediate jeopardy situation during the survey or as part of the exit conference at the end of the survey. This would give an HHA time to remove the immediate jeopardy and correct the deficiencies that gave rise to the immediate jeopardy finding. If the HHA fails to remove the immediate jeopardy situation, we would terminate the provider agreement no later than 23 days from the last day of the survey. Consistent with the notice process established for hospital emergency departments with deficiencies that pose immediate jeopardy (set out at § 489.53(b)), we are proposing at § 488.825 that if an immediate jeopardy situation was not resolved within 23 days because the HHA was unable or unwilling to correct deficiencies found during a survey, CMS would terminate the HHA’s provider agreement, using the termination procedures set out at § 489.53. We propose to amend § 489.53 by adding a new basis for termination at paragraph (a)(17), establishing that we would terminate an HHA’s provider agreement if the HHA failed to correct a deficiency or deficiencies within the required time frame.

The notice of our intent to impose a sanction as proposed § 488.825(b) would include the nature of the noncompliance, the sanctions to be imposed, the effective date of the sanction, opportunity for IDR and the right to appeal the determination leading to the sanction. In order to assure an HHA achieved prompt compliance, we expect that we would give HHAs written notice of impending enforcement actions against them as quickly as possible following the completion of a survey of any kind.

Finally, in proposed § 488.825(c), we would require an HHA whose provider agreement is terminated to appropriately and safely transfer its patients to another local HHA within 30 days of termination. The HHA would be responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The State would be required to assist the HHA with this process.

g. Actions When Deficiencies Are at the Condition-Level, But Do Not Pose Immediate Jeopardy (§ 488.830)

While section 1891(e)(2) of the Act provides for termination of the HHA’s provider agreement as an enforcement option in non-immediate jeopardy situations, we are interested in providing incentives for HHAs to achieve and maintain full compliance with the requirements specified under sections 1861(o) and 1891(a) of the Act before termination becomes necessary. Accordingly, our proposed regulations at § 488.830 reflect this enforcement policy and address the definition of “noncompliance,” provision of 15 day notice, criteria for continuation of payment, and termination time frame when there is no immediate jeopardy.

The statute does not require CMS to discontinue alternative sanctions when it proposes to terminate an HHA’s participation in Medicare; thus, these sanctions, if imposed, could continue while CMS initiated termination proceedings. Therefore, alternative sanctions could be imposed before the termination became effective, but could not continue for a period that exceeded six months. Also, to protect the health and safety of individuals receiving services from the HHA, alternative sanctions would apply until the HHA achieved compliance or had its Medicare participation terminated. For example, the suspension of payment sanction would end when the HHA corrected all condition-level deficiencies or was terminated.

We propose in § 488.830(b) that for a deficiency or deficiencies that do not pose immediate jeopardy, we would give the HHA at least 15 days advance notice of any proposed sanctions, except CMP, which would remain effective until the effective date of an impending termination (at 6 months) or until the HHA achieved compliance with CoPs, whichever was earlier. This is consistent with the general rule for providers and suppliers in § 489.53(d).

Section 1891(f)(3) of the Act provides that the Secretary shall develop and implement specific procedures for determining the conditions under which

alternative sanctions are to be applied, including the amount of any penalties and the severity of each sanction. The following sections describe each possible sanction and procedures for imposing them.

Finally, in proposed § 488.830(e), we would require an HHA whose provider agreement is terminated to appropriately and safely transfer its patients to another local HHA within 30 days of termination. The HHA would be responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The State would be required to assist the HHA with this process.

h. Temporary Management § 488.835

We are proposing in § 488.835 when and how CMS applies temporary management, the duration of this sanction, and the payment procedures for temporary managers. We propose that temporary management means the temporary appointment by CMS or a CMS authorized agent of an authorized substitute manager or administrator (based on qualifications described in § 484.4) who would be under the direction of the HHA's governing body and who would have authority to hire, terminate or reassign staff, obligate HHA funds, alter HHA procedures, and manage the HHA to correct deficiencies identified in the HHA's operation. We could impose temporary management when we determine that an HHA has condition-level deficiencies and that the deficiencies or the management limitations of the HHA are likely to impair the HHA's ability to correct the deficiencies and return the HHA to full compliance with the CoPs within the required timeframe. We would impose temporary management to bring an HHA into compliance with program requirements in non-IJ cases within six months, as we propose in § 488.835(c). We would also choose to impose temporary management as a sanction for deficiencies that posed immediate jeopardy to patient health and safety, as provided under proposed § 488.825(a)(3).

When temporary management is imposed, CMS would consider the HHA or SA's recommendation for a temporary manager when making the appointment. The individual appointed as a temporary manager would be required to have work experience and education that would qualify such individual to oversee the correction of deficiencies so that the HHA could achieve substantial compliance with the Medicare requirements. Each State Survey Agency will maintain a list of

recommended individuals who would be eligible to serve as temporary managers, and annually submit the list to CMS.

If the HHA refused to relinquish authority and control to the temporary manager, we would terminate the HHA's provider agreement. If a temporary manager was appointed, but the HHA failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the HHA's Medicare participation would be terminated. Additionally, if the HHA resumes management control without CMS's approval, it would be deemed to be a failure to relinquish authority and control to the temporary manager and we would impose termination and could impose any additional sanctions. The appointment of a temporary manager would not relieve the HHA of its responsibility to achieve compliance.

We propose in § 488.835(c) that temporary management would end when:

- We determined that the HHA was in compliance with all CoPs and had the capability to remain in full compliance;
- The HHA provider agreement was terminated; or
- The HHA resumed management control without CMS approval.

We believe that the proposed regulations at § 488.805 and § 488.835 would provide the temporary manager with the authority necessary to manage the HHA and cause positive changes. The temporary manager would have the authority to hire, terminate, or reassign staff; obligate HHA funds; alter HHA policies and procedures; and otherwise manage an HHA to correct deficiencies identified in the HHA's operations. Temporary management would be provided at the HHA's expense. Before the temporary manager was installed, the HHA would have to agree to pay his/her salary directly for the duration of the appointment. We believe that the responsibility for the HHA to pay the expenses of the temporary manager is an inherent management responsibility of the agency for which the HHA is regularly reimbursed by Medicare and Congress, pursuant to section 1891(e)(1), though such temporary outside management might be necessary in some cases to bring the HHA back into compliance with the conditions of participation. We propose that the salary for the temporary manager would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type, based on the based on the Geographic Guide by the Department of Labor (BLS Wage Data by Area and Occupation). In addition, the

HHA would have to pay for any additional costs that would have reasonably been incurred if such person had been in an employment relationship, and any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State. An HHA's failure to pay the salary of the temporary manager would be considered by CMS to be a failure to relinquish authority and control to temporary management.

i. Suspension of Payment for All New Admissions and New Payment Episodes § 488.840

We are proposing at § 488.840 regulations describing when and how CMS would apply a suspension of payment for new Medicare admissions and new PPS episodes of care. If an HHA had a condition-level deficiency or deficiencies (regardless of whether or not immediate jeopardy exists), we would suspend payments for new Medicare patient admissions to the HHA that were made on or after the effective date of the sanction. The suspension of payment would be for a period not to exceed six months and would end when the HHA either achieved substantial compliance or was terminated. Suspension of payment for new patient admissions and for new payment episodes that occurred on or after the effective date of the sanction could be imposed anytime an HHA was found to be out of substantial compliance. The CMS would provide the HHA with written notice of non-compliance at least two calendar days before the effective date of the sanction in immediate jeopardy situations (proposed § 488.825(b)) or at least 15 calendar days before the effective date of the sanction in non-immediate jeopardy situations (proposed § 488.830(b)). Our notice of suspension of payment for new admissions and new payment episodes would include the following: the nature of the non-compliance; the effective date of the sanction; and the right to appeal the determination leading to the sanction.

We propose to define a "new admission" in § 488.805 as the following:

- A patient who is admitted or readmitted to the HHA under Medicare on or after the effective date of a suspension of payment sanction; or
- A new payment episode that occurs on or after the effective date of a suspension of payment sanction. We have expanded the definition of "new admission" to include new payment episodes because we believe that each new payment episode (the 60 day

payment episode of HHA care) marks the beginning of a new assessment and a new care plan for the patient.

Furthermore, patients who are admitted before the effective date of the suspension and who have temporarily interrupted their treatment in the middle of a payment episode but are not discharged would not be subject to the suspension of payment.

Further, section 1891(f)(2)(C) of the Act provides that a suspension of payment sanction shall terminate when CMS finds that the HHA is in substantial compliance with all of the requirements specified in, or developed in accordance with, sections 1861(o) and 1891(a) of the Act. That is, the suspension of payment sanction would end when the HHA was determined to have corrected all condition-level deficiencies, or upon termination, whichever is earlier.

We would notify the HHA of the imposition of this sanction under proposed § 488.840(b)(1). Once such a sanction was imposed, we propose that the HHA would be required to notify any new patient admission and patients with new payment episodes that Medicare payment might not be available to this HHA because of the imposed suspension before care could be initiated. Moreover, the HHA would be precluded from charging the Medicare patient for those services unless it could show that, before initiating or continuing care, it had notified the patient or his/her representative both orally and in writing in a language that the patient or representative could understand, that Medicare payment might not be available. The suspension of payment would end when CMS terminated the provider agreement or CMS found, in accordance with 1891(f)(2)(C) of the Act, the HHA to be in compliance with all CoPs.

In proposed § 488.840(b)(3) in accordance with section 1891(f)(2)(C) of the Act, if CMS terminated the provider agreement, or if the HHA was in substantial compliance with the CoPs (as determined by CMS), the HHA would not be eligible for any payments for services provided to new Medicare patients admitted during the time the suspension was in effect, or for existing Medicare patients beginning a new payment episode during their care. This policy would be consistent with the legislative history of OBRA '87, which states that "suspended payments [are] not [to] be repaid to any agency once it has come back into compliance and the suspension has been lifted. It is the Committee's belief that if such repayment were permitted, there would

be little incentive for deficient agencies to come back into compliance as quickly as possible." See H.R. Rep. No. 100–391(I) at 423 (1987). In accordance with the Committee's intent, we would construe the term "suspend" to mean to temporarily stop Medicare payments, without the possibility of recovering the suspended payments. If compliance with the CoPs was achieved, we would resume payment to the HHA prospectively from the date that CMS had determined correction.

In proposed § 488.840(c), the suspension of payment would end when CMS terminates the provider agreement or CMS finds, in accordance with section 1891(f)(2)(C) of the Act, the HHA to be in substantial compliance with all of the CoPs.

j. Civil Money Penalties (CMPs) § 488.845

We are proposing in § 488.845 rules for imposition of CMPs. Under sections 1891(e) and 1891(f)(2)(A)(i) of the Act, CMS may impose a CMP against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose immediate jeopardy to patient health and safety. We could also impose a civil money penalty for the number of days of immediate jeopardy. The CMP amount cannot exceed \$10,000 for each day of non-compliance. A deficiency found during a survey at a parent HHA or any of its branches results in a noncompliance issue for the entire HHA, which can be subject to the imposition of a CMP.

In this section, we propose both a "per day" and a "per instance" CMP at § 488.845(a). The per day CMP would be imposed for each day of noncompliance with the CoPs. Additionally, should a survey identify a particular instance or instances of noncompliance during a survey, we propose to impose a CMP for that instance or those individual instances of noncompliance. We propose to define "per instance" in § 488.805 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction. While there may be a single event which leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one CMP imposed during a survey. For penalties imposed per instance of noncompliance, we are proposing penalties from \$1,000 to \$10,000 per instance. Such penalties would be assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where

the noncompliance was corrected during the onsite survey.

Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. Thus, we believe that each deficiency would fit into a range of CMP amounts, which we discuss below.

We are proposing that we would consider the following factors when determining a CMP amount, in addition to those factors that we would consider when choosing a type of sanction proposed in § 488.815:

- The size of the agency and its resources.
- The availability of other HHAs within a region, including service availability in a given region.
- Accurate and credible resources such as PECOS and Medicare cost reports and claims information, that provide information on the operations and the resources of the HHA.
- Evidence that the HHA has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety. When several instances of noncompliance would be identified at a survey, more than one per-day or per instance CMP could be imposed as long as the total CMP did not exceed \$10,000 per day. Also, a per-day and a per-instance CMP would not be imposed simultaneously for the same deficiency.

At proposed § 488.845(b)(2), we would give ourselves the discretion to increase or reduce the amount of the CMP during the period of noncompliance depending on whether the level of noncompliance had changed at the time of a revisit survey. CMS could increase a CMP in increments based upon an HHA's inability or unwillingness to correct deficiencies, the presence of a system wide failure in the provision of quality care or a determination of immediate jeopardy with potential for harm. CMS could also decrease a CMP in increments to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA is not yet in full compliance if earnest efforts have been made to address the causes of deficiencies and sustain improvement. If an HHA cured the immediate jeopardy situation, but not the

condition-level deficiencies, we could reduce penalties from the upper range to a lower range imposed in non-immediate jeopardy situations.

However, section 1891(f)(2)(A)(i) of the Act specifies that the sanctions shall include a CMP in an amount not to exceed \$10,000 for each day of noncompliance. Therefore, we are proposing at § 488.845(b)(2)(iii) that no CMP assessment exceed \$10,000 per day of noncompliance. Because the Act directs us to establish the amounts of fines and the levels of severity, we propose to establish a three-tier system with subcategories which would establish the amount of a CMP. In proposed § 488.845(b)(3), (b)(4), and (b)(5), we propose the following would

be ranges of civil money penalty amounts based on three levels of seriousness—upper, middle and lower:

- Upper range—For a deficiency that poses immediate jeopardy to patient health and safety, we would assess a penalty within the range of \$8,500 to \$10,000 per day of condition level noncompliance.
- Middle range—For repeat and/or a condition-level deficiency that did not pose immediate jeopardy, but is directly related to poor quality patient care outcomes, we would assess a penalty within the range of \$2,500 to \$8,500 per day of noncompliance with the CoPs.
- Lower range—For repeated and/or condition-level deficiencies that did not constitute immediate jeopardy and were

deficiencies in structures or processes that did not directly relate to poor quality patient care, we would assess a penalty within the range of \$500 to \$4,000 per day of noncompliance.

Table is displayed to represent the relationship between the existing survey protocols and proposed ranges of CMP imposition. This table distinguishes proposed ranges based in IJ, Non-IJ, repeat deficiency and first time deficiency. It uses the terminology of structure, process, and outcomes, which is used in the quality improvement field as a hierarchy of measures. This structure would be further developed in the policy guidance stage and is presented for illustrative purposes only.

TABLE 24—CMP

[Per day]

Level of seriousness	CMP fine ranges/amount
Immediate Jeopardy (Non-IJ) Patient Care Outcomes	\$8,500–\$10,000; 2,500–8,500; 8,500
Repeat Deficiency	
42 CFR 484.18 Acceptance of Patients, Plan of Care, & Medical Supervision.	
42 CFR 484.30 Skilled Nursing Services.	
42 CFR 484.34 Medical Social Services.	
42 CFR 484.36 Home Health Aide Services.	
42 CFR 484.55 Comprehensive Assessment of Patients.	
First time deficiency	5,000
42 CFR 484.18 Acceptance of Patients, Plan of Care, & Medical Supervision.	
42 CFR 484.30 Skilled Nursing Services.	
42 CFR 484.34 Medical Social Services.	
42 CFR 484.36 Home Health Aide Services.	
42 CFR 484.55 Comprehensive Assessment of Patients.	
Structure or process issues	2,500
42 CFR 484.10 Patient Rights.	
42 CFR 484.12 Compliance With Federal, State and Local Laws, Disclosure and Ownership Information, and Accepted Professional Standards and Principles.	
42 CFR 484.14 Organization, Services, and Administration.	
42 CFR 484.48 Clinical Records.	
Non-IJ Structure/process	500–4,000
Repeat Deficiency at revisit or from prior survey	4,000
42 CFR 484.11 Confidential OASIS Information.	
42 CFR 484.16 Group of Professional Personnel.	
42 CFR 484.20 Reporting OASIS Information.	
42 CFR 484.52 Evaluation of the agency's program.	
First time deficiency	500–3,000
42 CFR 484.11 Confidential OASIS Information.	
42 CFR 484.16 Group of Professional Personnel.	
42 CFR 484.20 Reporting OASIS Information.	
42 CFR 484.52 Evaluation of the agency's program.	
Other structure or process issues	500–3,000
Non patient care issues 42 CFR 484.34 Medical Social Services.	
42 CFR 484.38 Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services.	

If we imposed a CMP, we would send the HHA written notification of the intent to impose it, including the amount of the CMP being imposed and the proposed effective date of the sanction. After a final agency determination is made, a final notice would be sent with the final amount due and the rate of interest to be charged on unpaid balances (as

published quarterly in the **Federal Register**). The notice would include reference to the nature of the noncompliance; the statutory basis for the penalty; the proposed amount of the penalty per day/instance of noncompliance; the criteria we considered when determining the amount per-day or per-instance; the date on which the penalty would begin to

accrue; when the penalty would stop accruing; when the penalty would be collected; and instructions for responding to the notice, including a statement of the HHA's appeal rights, including an opportunity to participate in the proposed IDR process and, as discussed below, the right to a hearing, and the implications of waiving a hearing. In accordance with our existing

regulations at § 498.22(b)(3) and § 498.40 and at proposed § 488.845(c)(2), once a notice of intent to impose the CMP had been sent to the HHA, the HHA would have 60 days from the receipt of the notice to request an administrative hearing under § 498.40 or waive its right to an administrative hearing in writing and receive a 35 percent reduction in the CMP amount. This reduction would be offered to encourage HHAs to address deficiencies more expeditiously and to save the cost of hearings and appeals. Upon such reduction, the CMP would be due within 15 days of the receipt of the HHA's written request for waiver. The HHA could waive its right to a hearing in writing within 60 calendar days from the date of the notice initial determination.

The per-day CMP would begin to accrue on the day of the survey that identified the HHA noncompliance, and would end on the date of correction of all deficiencies, or the date of termination. We are proposing at 488.845(d) that in immediate jeopardy cases, if the immediate jeopardy was not removed, the CMP would continue to accrue until CMS terminated the provider agreement (within 23 calendar days after the last day of the survey which first identified the immediate jeopardy). Under proposed 488.845(d)(4), if immediate jeopardy did not exist, the CMP would continue to accrue until the HHA achieved substantial compliance or until we terminated the provider agreement. Additionally, we are proposing at § 488.845(d)(2) that the per-day and per-instance CMP would not be imposed simultaneously in conjunction with a survey. In no instance will the period of noncompliance be allowed to extend beyond 6 months from the last day of the original survey that determined noncompliance. If the HHA has not achieved compliance with the CoPs within those 6 months, we would terminate the HHA. The accrual of the CMP stops on the day the HHA provider agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

Total CMP amounts would be computed after a final agency determination; that is, after: (1) Compliance was verified; (2) the HHA provider agreement was involuntarily terminated; or (3) administrative remedies had been exhausted. If the HHA had achieved substantial compliance, we would send a separate notice to the HHA describing the amount of penalty per day, the number of days the penalty accrued, the total amount due, the due date of the penalty,

and the interest rate for any unpaid balance. For a per-instance CMP, we would include the amount of the penalty, the total amount due, the due date of the penalty, and the rate of interest for any unpaid balance. In the case of the HHA that was terminated, we would send the HHA any CMP notice of final amount or a due and payable notice information in the termination notice, as described in § 489.53(d).

In proposed § 488.845(f), a CMP would become due and payable 15 days from the notice of final administrative decision, which is after:

- The time to appeal had expired without the HHA appealing its initial determination;
- CMS received a request from the HHA waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge and/or DAB Appellate Board upheld CMS's determinations; or
- After an HHA achieves substantial compliance; or
- The HHA was terminated from the program and no appeal request was received.

A request for hearing would not delay the imposition of the CMP, but would only affect the collection of any final amounts due to CMP. If an HHA timely waived its right to a hearing under proposed § 488.845(c)(2)(ii), we would reduce the final CMP amount by 35 percent. This reduction would be reflected once the CMP stops accruing: when the HHA achieved compliance before we received its request to waive a hearing, or the effective date of the termination occurred before we received the waiver request.

The final CMP receivable amount would be determined when the per-day CMP accrual period ended (either when the HHA achieved compliance or was terminated).

An HHA has three options for action following the imposition of a penalty:

- The HHA could pay the fine in full for all CMPs imposed prior to the date a CMP is due and payable.
- The HHA could request a hearing based on the determination of noncompliance with Medicare requirements. Within 60 days of receipt of the notice of imposition of a penalty, the HHA could file a request directly to the Departmental Appeals Board in the Office of the Secretary, Department of Health and Human Services with a copy to the State and CMS. In accordance with § 498.40(b), the HHA's appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which

the agency disagreed, and the specific bases for contending that the survey findings and determinations were invalid. A hearing would be completed before any penalty was collected. However, sanctions would continue regardless of the timing of any appeals proceedings if the HHA had not met the CoPs. Requesting an appeal would not delay or end the imposition of a sanction.

A CMP would begin to accrue on the date of the survey which identified the noncompliance. These include penalties imposed on a per day basis, as well as penalties imposed per instance of noncompliance.

Offsets

To maintain consistency in recovering a CMP among other types of providers who are subject to a CMP, we propose that the amount of any penalty, when determined, could be deducted (offset) from any sum CMS or the State Medicaid Agency owed to the HHA. Interest would be assessed on the unpaid balance of the penalty beginning on the due date. We propose that the rate of interest assessed on any unpaid balance would be based on the Medicare interest rate published quarterly in the **Federal Register**, as specified in § 405.378(d). We would recover a CMP as set forth in section 1128A(f) of the Act. Those CMP receipts not recovered due to HHA failure to pay or inadequate funds for offset will be collected through the Debt Collection Improvement Act of 1996 which requires all debt owed to any Federal agency that is more than 180 days delinquent to be transferred to the Department of the Treasury for debt collection services.

If payment was not received by the established due date, we propose to initiate action to collect the CMP through offset of monies owed or owing to the HHA. To initiate such an offset, we would instruct the appropriate Medicare Administrative Contractors/ Fiscal Intermediaries and, when applicable, the State Medicaid agencies to deduct unpaid CMP balances from any money owed to the agency.

Disbursement of Recovered CMP Funds

Under § 488.845(g)(1), we propose to divide the CMP amounts recovered and any corresponding interest between the Medicare and Medicaid programs, based on a proportion that is commensurate with the comparative Federal expenditures under Titles XVIII and XIX of the Act, using an average of years 2007 to 2009 based on Medicaid Statistical Information System (MSIS) and HHA Prospective Payment System

(PPS) claims. Based on the proportions of HHA claims attributed to Medicare and Medicaid, respectively, for the FY 2007–2009 period, approximately 63 percent of the CMP amounts recovered would be deposited as miscellaneous receipts to the U.S. Department of the Treasury and approximately 37 percent will be returned to the State Medicaid Agency to improve the quality of care for those who need home-based care. We propose that, beginning one year after these rules are finalized and become effective, these proportions would be updated annually based on the most recent 3 year period for which CMS determined that the Medicare and Medicaid expenditure data were essentially complete.

Costs of Home Health Surveys

Consistent with the proposed disbursement to States of a portion of federally imposed-CMP amounts collected, this proposed rule would provide that State Medicaid programs share in the cost of HHA surveys for those HHAs that are Medicaid-certified. We propose to amend § 431.610(g) (Relations with standard-setting and survey agencies) to apply to HHA surveys the same cost accounting principles that are now applied to nursing homes. In other words, we are adding a reference to HHAs, along with nursing facilities (NFs) and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs). We project the initial cost to the Medicaid program would be approximately 37 percent of the cost of surveys for dually-certified programs, based on the same cost allocation methodology we propose to use for the disbursement to States of CMP collections, as described above. We request comment on the new requirement for State Medicaid programs and the methodology for calculating the State share of both survey costs and CMP disbursement.

k. Directed Plan of Correction § 488.850

We are proposing in § 488.850 a directed plan of correction as an available sanction. This sanction is a part of the current nursing home alternative sanction procedures and has been an effective tool to encourage correction of deficient practices. Specifically, CMS would be able to impose a directed plan of correction on an HHA which is out of compliance with the Conditions of Participation. A directed plan of correction sanction would require the HHA to take specific actions in order to correct the deficient practice(s) if the HHA failed to submit an acceptable plan of correction. As proposed in § 488.850(b)(2) an HHA's

directed plan of correction would have to be developed by us or by the temporary manager, with our approval. The directed plan of correction would set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes, and the specific date the HHA would be expected to achieve such outcomes. For example, a directed plan of correction for a deficiency finding involving poor drug regimen review would likely indicate that the HHA would be required to: (1) Develop policies and procedures for assessing each patient and before accepting any new admissions; (2) assess every patient's drug regimen according to the regulations at § 484.55(c); and (3) train staff in correct policies and procedures and implement them. The HHA would be responsible for achieving compliance. If the HHA failed to achieve compliance within the timeframes specified in the directed plan of correction, we would impose one or more additional alternative sanctions until the HHA achieved compliance or was terminated from the Medicare program. Before imposing this sanction, we would provide appropriate notice to the HHA of this sanction under proposed § 488.810(f).

l. Directed In-Service Training § 488.855

We are proposing in § 488.855 when and how CMS would conduct directed in-service training for HHAs with deficiencies. Some compliance problems are a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and expectations of favorable patient outcomes. In proposed § 488.855(a) directed in-service training would be used in situations where staff performance resulted in deficient practices. A directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes. Directed in-service training would be imposed if CMS determined that the HHA had a deficiency or deficiencies that indicated noncompliance, and that staff education was likely to correct the deficient practice(s). It could be imposed alone or in addition to other alternative sanctions.

At proposed § 488.855(a)(3), HHAs would be required to use in-service programs conducted by instructors with an in-depth knowledge of the area(s) that would require specific training, so that positive changes would be achieved and maintained. HHAs would be required to participate in programs developed by well-established centers of

health services education and training. These centers include, but are not limited to, schools of medicine or nursing, area health education centers, and centers for aging. We would only recommend possible training locations to an HHA and not require that the HHA utilize a specific school/center/provider. The HHA would be required to bear any resulting expenses. The ultimate evaluation of the training program would be in the demonstrated competencies of the HHA's staff in achieving the desired patient care outcomes after completion of the training program. In proposed § 488.855(b) if the HHA did not achieve compliance after such training, we could impose one or more additional sanctions. The HHA itself would pay for the directed in-service training for its staff.

m. Continuation of Payments to HHAs With Deficiencies § 488.860

We propose in § 488.860 rules concerning the continuation of Medicare payments to HHAs with condition-level deficiencies. Section 1891(e)(4) of the Act provides that the Secretary may continue Medicare payments to HHAs not in compliance with the conditions for participation for up to six months if:

- The survey agency finds it more appropriate to impose alternative sanctions to assure compliance with program requirements than to terminate the HHA from the Medicare program;
- The HHA submits a plan of correction to the Secretary, and to the office the Secretary has delegated the authority to approve the plan of correction; and
- The HHA agrees to repay the Federal government the payments under this arrangement should the HHA fail to take the corrective action as set forth in its approved plan of correction by the time of the revisit.

We propose these same three criteria in § 488.860(a). If any of these three requirements set forth in the Act and in our proposed rule are not met, an HHA with condition-level deficiencies would not receive any Federal payments from the time that deficiencies were initially identified. We would terminate the agreement before the end of the 6-month correction period in accordance with proposed § 488.865 if the requirements proposed at § 488.860(a)(1) are not met. If any sanctions were also imposed, they would stop accruing or end when the HHA achieves compliance with all requirements, or when the HHA's provider agreement is terminated, whichever is earlier. We would terminate the HHA's provider agreement

if the HHA is not in compliance with the CoPs within 6 months of the last day of the survey. Finally, if an HHA provides an acceptable plan of correction but cannot achieve compliance with the CoPs within 6 months of the last day of the survey, we are proposing in § 488.830(d) that CMS would terminate the provider agreement.

n. Termination of Provider Agreement (§ 488.865)

At § 488.865(a), we would address the termination of an HHA's Medicare provider agreement, as well as the effect of such termination. Termination of the provider agreement would end all payments to the HHA, including any payments that were continued under proposed § 488.860. Termination would also end any alternative sanctions imposed against the HHA, regardless of any proposed timeframes for the sanction(s) originally specified. In proposed § 488.865(b) we would terminate the provider agreement if (1) the HHA failed to correct condition-level deficiencies within six months unless the deficiencies constitute immediate jeopardy; (2) the HHA failed to submit an acceptable plan of correction for approval by us under proposed § 488.810; or (3) the HHA failed to relinquish control to the temporary manager, if that sanction is imposed or (4) the HHA failed to meet the eligibility criteria for continuation of payments under proposed § 488.860. If CMS or the SA determined deficiencies existed which posed immediate jeopardy to patient health and safety, we would terminate the provider agreement. The provider could also voluntarily terminate its agreement. CMS and the SA would, if necessary, work with all Medicare-approved HHAs that were terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA.

The procedures for terminating a provider agreement are set forth in § 489.53 and we are proposing to continue to use those procedures for an enforcement action terminating an HHA at § 488.865(d). These procedures form the basis for termination by CMS and specify a provider's notice and appeal rights. Under § 488.865(e), we propose that the HHA could appeal the termination of its provider agreement in accordance with 42 CFR part 498. We are also proposing to add an exception to the general notice provision as well as to amend § 489.53(a) by adding a new paragraph (17) establishing that when an HHA failed to correct any deficiency (either standard-level or condition-

level), we could terminate its provider agreement. The notification requirements in § 489.53(d)(1) requires that CMS give notice to any provider and the public at least 15 days before the effective date of a termination of a provider agreement. We are proposing a new clause in § 489.53(d)(2)(iii) which would provide for a timing exception to this general notice rule. Specifically, we propose that for HHA terminations based on deficiencies that posed immediate jeopardy to patient health and safety, we would give notice to the HHA of such termination at least 2 days before the effective date of the termination. As currently provided in § 489.53(d)(4), we would give concurrent notice to the public when such termination occurred.

C. Provider Agreements and Supplier Approval

We are also proposing to amend § 498.3, Scope and applicability, by revising paragraphs (b)(13), (b)(14) introductory text, (b)(14)(i), and (d)(10) to include specific reference to HHAs and to cross-refer to our proposed regulation at proposed § 488.740 concerning appeals.

D. Solicitation of Comments

Presently, we are required only to give notice of an HHA termination to the public 15 days before the effective date of an involuntary termination. We are soliciting comments related to additional public notices. We are considering that when a suspension of payments for new admissions and new payment episodes or a civil money penalty is imposed, we could, at our discretion, issue a public notice. The issuance of additional publicly-reported notices when certain sanctions are imposed would offer information to patients who were choosing a provider of home health services, as well as to current recipients of home health care. A home health patient does not necessarily know when a survey has been conducted at an HHA and if deficiencies had been determined or any sanctions imposed unless a surveyor visited the patient during a survey or the patient requested a copy of a Statement of Deficiencies from the SA or HHA. We are also soliciting comments on the proposed definition of a "per instance" of noncompliance when imposing a CMP sanction.

VI. Collection of Information Requirements

While this proposed rule contains information collection requirements, this rule does not add new or revise any of the existing information collection

requirements or burden with regard to: § 424.22(a) (OCN 0938–1083), § 488.710 (OCN 0938–0355; CMS–1515 and CMS–1572), and § 488.810(e) (OCN 0938–0391; CMS–2567). Nor does this proposed rule revise any of the existing information collection requirements or burden with regard to OASIS as discussed in preamble section III.C.3. and approved under OCN 0938–0760 or Home Health Care CAHPS as discussed in the same preamble section but approved under OCN 0938–1066. All of the requirements and burden estimates associated with these collections are currently approved by OMB and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

In § 431.610, HHAs would be added to the survey agency provision concerning State Plans. Since the State Medicaid Plans already include a provision that the State Survey Agencies will have qualified personnel perform onsite inspections as appropriate, we believe that this requirement is in the current plans and is inclusive of all Medicaid work being performed by the State Survey Agency. Consequently, the provision would not require a specific revision to any State Plans and would not impose any additional burden to States.

In § 488.710, for each HHA the SA must (existing requirement) conduct standard surveys according to their agreements with CMS under sections 1864 and 1891(c)(1) of the Act. CMS believes that the additional survey agency administrative activity required to impose alternative sanctions created by this rule will not generate a significant amount of additional paperwork burden at the State survey agency or HHA level. Imposing sanctions may require that states engage in some additional communication and carry out follow-up surveys, and CMS Regional Offices may need additional time for determining, imposing and tracking sanctions. In estimating appeal volume and costs, we note that in 2010 only 260 providers out of 11,821 had condition level-deficiencies, and only seven of these involved immediate jeopardy situations. Further, the impact of additional activity on State budgets will be negligible because we estimate that about 63 percent of the cost attributable to Medicare will be paid to survey agencies under the authority provided by section 1864 for Medicare surveys; and Federal Medicaid funds will generally pay 75 percent of the remaining 37 percent share of costs, since there is an increased Federal match for State survey activities as

referenced in section 1903(a)(2) of the Act. In addition, the State will benefit financially by the additional CMP funds returned to the State to use for the benefit of home based care participants.

SAs survey HHAs to determine compliance with the CoPs under part 484 and follow the guidance contained in the State Operations Manual, S&C Memoranda, and Interpretive Guidelines. This rule would serve to codify some existing CMS policies while proposing new requirements which would be consistent with OBRA '87 mandates discussed in the Background and Statutory Authority section. State Surveyor recordkeeping requirements already exist as Forms CMS-1515 and CMS-1572 (OMB control number known as information collection 0938-0355) and CMS-2567 (OMB# 938-0391). CMS anticipates enhancing survey protocols and Interpretive Guidelines and providing additional S&C Memoranda and Surveyor Training in response to the issuance of new regulations. CMS would revise these currently approved collections as necessary in accordance with the final rule.

In § 488.735, State and Federal surveyors would be required to complete the CMS-sponsored Basic HHA Surveyor Training Course before they can serve on a HHA survey team. The CMS Central Office currently provides national training to all State surveyors for all of the provider types that are surveyed for Medicare and Medicaid. Those training courses are funded entirely by the Central Office and there is no burden to States since our annual budgets to the States (for the performance of survey activities) includes the cost of the salaries and the travel for participating in all national training courses. These training courses are designed to teach the surveyors how to conduct the survey process in accordance with the applicable regulations and associated Interpretive Guidance. During the course of the survey, all of the data collection tools that may be used (see the reference to CMS-1515, -1572, and -2567 above) have been approved by OMB through the PRA process.

Section 488.810(e) requires each HHA that has deficiencies constituting noncompliance to submit a plan of correction for approval by CMS. This is a current requirement for both standard and condition level deficiencies, so the burden associated with this requirement that is above and beyond the existing effort put forth by the HHA is to prepare and submit a plan of correction would be to notify their governing body, potentially prepare for IDR or to issue a

check for a CMP. While there is paperwork burden associated with this plan of correction requirement, it is already required and currently approved under OMB# 0938-0391 (CMS-2567).

Information Collection Requests Exempt From the Paperwork Reduction Act

In accordance with 5 CFR 1320.4(a)(2) and (c), the following information collection activities are exempt from the requirements of the Paperwork Reduction Act since they are associated with administrative actions: (1) Section 488.745(a) regarding HHA request to dispute condition-level survey findings; (2) § 488.810(g) regarding appeals; (3) § 488.845(c)(2)(i) regarding the submission of a written request for a hearing or waiver of a hearing; (4) § 488.840(b)(1)(ii) regarding HHA disclosure requirements; (5) § 488.845(c) regarding hearings; and (6) § 488.855 regarding HHA deficiencies and directed in-service training.

The information collection requirement in § 488.825(c) regarding the transfer of care is exempt from the requirements of the Paperwork Reduction Act since it is associated with an administrative action (5 CFR 1320.4(a)(2) and (c)) and we estimate fewer than ten provider agreements will be terminated annually (5 CFR 1320.3(c)).

Information Collection Requests Regarding the Quality Reporting for Hospices

Within the preamble of this proposed rule, in section IV, we note that section 3004 of the Affordable Care Act amends the Social Security Act (the Act) to authorize a quality reporting program for hospices. Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. As added by section 3004(c), new section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by two percentage points for any hospice that does not comply with the quality data submission requirements with respect to that fiscal year.

In implementing the Hospice quality reporting program, CMS seeks to collect measure-related information with as little burden to the providers as possible and which reflects the full spectrum of quality performance. Our purpose in collecting this data is to help achieve better health care and improve health through the widespread dissemination and use of performance information.

The Hospice Data Submission form intended for data submission by January 31, 2013 (for the structural measure related to patient care-focused QAPI indicators) and for data submission by April 1, 2013 (for the NQF #0209 measure related to pain) has been made available for public comment through a 60-day **Federal Register** notice that published on June 4, 2012 (77 FR 32977). A follow up 30-day notice will publish after the 60-day comment period closes. Technically, the form is not associated with this proposed rule but is discussed within this document to provide background information.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), 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. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule does not reach the economic threshold and thus is not considered a major rule. In accordance with the provisions of Executive Order

12866, this regulation was reviewed by the Office of Management and Budget.

B. Statement of Need

This proposed rule adheres to the following statutory requirements. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled "Prospective Payment For Home Health Services". Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(5) of the Act, as amended by section 3131 of the Affordable Care 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 3131 of the Affordable Care Act requires that 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, receive an increase of 3 percent the payment amount otherwise made under section 1895 of the Act.

C. Overall Impact

The update set forth in this proposed rule applies to Medicare payments under HH PPS in CY 2013. Accordingly, the following analysis describes the impact in CY 2013 only. We estimate that the net impact of the proposals in this rule is approximately \$20 million in CY 2013 savings. The \$20 million impact reflects the distributional effects of an updated wage index (\$70 million decrease) the +1.5 percent HH payment update (\$300 million increase), and the -1.32 percent case-mix adjustment applicable to the national standardized 60-day episode rates (\$250 million decrease). The \$20 million in savings is reflected in the first row of column 3 of Table 25 as 0.10 percent decrease in expenditures when comparing the current CY 2012 HH PPS to the proposed CY 2013 HH PPS. 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 \$7.0 million to \$34.5 million in any 1 year. For the purposes of the RFA, our updated data show that approximately 98 percent of HHAs are considered to be small businesses according to the Small Business Administration's size standards with total revenues of \$13.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. We define small HHAs as either non-profit or proprietary with total revenues of \$13.5 million or less in any 1 year. We estimate that approximately 18 percent of HHAs are classified as non-profit. Analysis of Medicare claims data reveals a 0.11 percent decrease in estimated payments to small HHAs in CY 2013.

A discussion on the alternatives considered is presented in section V.E. below. The following analysis, with the rest of the preamble, constitutes our initial RFA analysis. We solicit comment on the RFA analysis provided.

In this proposed rule, we have stated that our analysis reveals that nominal case-mix continues to grow under the HH PPS. Specifically, nominal case-mix has grown from the 19.03 percent growth identified in our analysis for CY 2012 rulemaking to 20.08 percent for this year's rulemaking (see further discussion in section III.A.). As such, we believe it is appropriate to reduce the HH PPS rates using the 1.32 percent payment reduction promulgated in the CY 2012 HH PPS Final Rule (76 FR 68532) in moving towards more accurate payment for the delivery of home health services. Our analysis shows that smaller HHAs are impacted slightly more than are larger HHAs by the proposed provisions of this rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule applies to HHAs. Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately \$139 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments in the aggregate, or by the private sector, of \$139 million or more.

D. Detailed Economic Analysis

This proposed rule sets forth updates to the HH PPS rates contained in the CY 2012 HH PPS final rule. The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based on Medicare claims from 2010. We note that certain events may combine to limit the scope

or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to

predict accurately the full scope of the impact upon HHAs.

Table 25 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule. For this analysis, we used linked home health claims and OASIS assessments; the claims represented a 100-percent sample of 60-day episodes occurring in CY 2010. The first column of Table 25 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the payment effects of the wage index only. The third column shows the payment effects of all the proposed policies outlined earlier in this rule. For CY 2013, the average impact for all

HHAs due to the effects of the wage index is a 0.34 percent decrease in payments. The overall impact for all HHAs, in estimated total payments from CY 2012 to CY 2013, is a decrease of approximately 0.10 percent.

As shown in Table 25, the combined effects of all of the changes vary by specific types of providers and by location. In general, facility-based, proprietary agencies in rural areas would be impacted positively as a result of the proposed provisions of this rule. In addition, free-standing, other volunteer/non-profit agencies and facility-based volunteer/non-profit agencies in urban areas would be impacted positively.

TABLE 25—PROPOSED HOME HEALTH AGENCY POLICY IMPACTS FOR CY 2013, BY FACILITY TYPE AND AREA OF THE COUNTRY

Group	Comparisons	
	Percent change due to the effects of the updated wage index (percent)	Impact of all CY 2013 policies ¹ (percent)
All Agencies	−0.34	−0.10
Type of Facility		
Free-Standing/Other Vol/NP	0.04	0.32
Free-Standing/Other Proprietary	−0.46	−0.23
Free-Standing/Other Government	−0.45	−0.19
Facility-Based Vol/NP	−0.06	0.20
Facility-Based Proprietary	−0.35	−0.11
Facility-Based Government	−0.46	−0.22
Subtotal: Freestanding	−0.36	−0.12
Subtotal: Facility-based	−0.13	0.13
Subtotal: Vol/NP	0.01	0.27
Subtotal: Proprietary	−0.45	−0.22
Subtotal: Government	−0.46	−0.20
Type of Facility (Rural * Only)		
Free-Standing/Other Vol/NP	−0.61	−0.36
Free-Standing/Other Proprietary	−0.83	−0.61
Free-Standing/Other Government	−0.56	−0.28
Facility-Based Vol/NP	−0.51	−0.26
Facility-Based Proprietary	0.16	0.39
Facility-Based Government	−0.56	−0.31
Type of Facility (Urban * Only)		
Free-Standing/Other Vol/NP	0.15	0.42
Free-Standing/Other Proprietary	−0.40	−0.17
Free-Standing/Other Government	−0.31	−0.07
Facility-Based Vol/NP	0.07	0.33
Facility-Based Proprietary	−0.58	−0.34
Facility-Based Government	−0.34	−0.10
Type of Facility (Urban* or Rural*)		
Rural	−0.72	−0.48
Urban	−0.26	−0.02
Facility Location: Region*		
North	0.17	0.45
South	−0.69	−0.45
Midwest	−0.25	−0.02
West	0.39	0.64
Outlying	−0.49	−0.25
Facility Location: Area of the Country		
New England	0.61	0.88
Mid Atlantic	−0.09	0.20
South Atlantic	−0.41	−0.17
East South Central	−1.12	−0.91
West South Central	−0.76	−0.53
East North Central	−0.32	−0.10

TABLE 25—PROPOSED HOME HEALTH AGENCY POLICY IMPACTS FOR CY 2013, BY FACILITY TYPE AND AREA OF THE COUNTRY—Continued

Group	Comparisons	Impact of all CY 2013 policies ¹ (percent)
	Percent change due to the effects of the updated wage index (percent)	
West North Central	0.11	0.35
Mountain	−0.56	−0.31
Pacific	0.82	1.06
Outlying	−0.49	−0.25
Facility Size: (Number of First Episodes)		
<100	−0.49	−0.26
100 to 249	−0.54	−0.31
250 to 499	−0.46	−0.22
500 to 999	−0.40	−0.17
1,000 or More	−0.08	0.18
Facility Size: (estimated total revenue)		
Small (estimated total revenue < \$13.5 million)	−0.34	−0.11
Large (estimated total revenue > \$13.5 million)	−0.18	0.12

Note: Based on a 100 percent sample of CY 2010 claims linked to OASIS assessments.

* Urban/rural status, for the purposes of these simulations, is based on the wage index on which episode payment is based. The wage index is based on the site of service of the beneficiary.

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.

¹ Percent change due to the effects of the updated wage index, the 1.5 percent proposed payment update, and the 1.32 percent case-mix adjustment.

E. Alternatives Considered

As described in section VI.C. above, if we implement the case-mix adjustment for CY 2013 along with the home health payment update and the updated wage index, the aggregate impact would be a net decrease of \$20 million in payments to HHAs, resulting from a \$70 million decrease due to the updated wage index, a \$300 million increase due to the home health payment update, and a \$250 million decrease from the 1.32 percent case-mix adjustment. If we were to not implement the 1.32 case-mix adjustment, Medicare would pay an estimated \$250 million more to HHAs in CY 2013, for a net increase of \$230 million in payments to HHAs (market basket update of \$300 million minus \$70 million due to the updated wage index). We believe that not implementing a case-mix adjustment, and paying out an additional \$250 million to HHAs when those additional payments are not reflective of HHAs treating sicker patients, would not be in line with the intent of the HH PPS, which is to pay accurately and appropriately for the delivery of home health services to Medicare beneficiaries.

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. We are committed to monitoring the accuracy of payments to HHAs, which includes the measurement of the increase in nominal case-mix, which is an increase in case-mix that is not due to patient acuity. As discussed in section III.A. of this rule, we have determined that there is a 20.08 percent nominal case-mix change from 2000 to 2010. For CY 2013, we propose to move forward with the 1.32 percent payment reduction to the national standardized 60-day episode rates as promulgated in the CY 2012 HH PPS final rule (76 FR 68532).

We believe that the alternative of not implementing a case-mix adjustment to the payment system in CY 2013 to account for the increase in case-mix that is not real would be detrimental to the integrity of the PPS. As discussed in section III.A. of this rule, because nominal case-mix continues to grow as we update our analysis with more current data and thus to date we have not accounted for all the increase in nominal case-mix growth, we believe it is appropriate to reduce HH PPS rates now, thereby paying more accurately for the delivery of home health services under the Medicare home health benefit. The other reduction to HH PPS

payments, a 1.0 percentage point reduction to the proposed CY 2013 home health market basket update, is discussed in this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi) of the Act (as amended by the Affordable Care Act).

We solicit comment on the alternatives considered in this analysis.

F. Survey and Enforcement Requirements for Home Health Agencies

The RFA requires agencies to analyze options for regulatory relief 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 \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed regulation would not have a significant economic impact on a substantial number of small entities. In 2010, out of a total of 11,814 HHAs enrolled in the Medicare program, only 260 HHA providers had the potential to be sanctioned based on noncompliance

with one or more CoPs. This would be 2.2 percent of the HHAs (small entities affected) which is less than 5 percent.

We believe the benefit would be in assuring public health and safety CMS believes this proposed rule will have a minor impact on HHAs and SAs. This minor rule determination was made by examining the following survey data for calendar year (CY) 2010 in the CMS Providing Data Quickly (PDQ) System: Survey Activity Report, the Citation Frequency Report, the Condition-Level Deficiencies Report and the Active Provider Count Report(s).

Our data below reflects the probability of low impact for monetary sanctions. In any given year approximately 11,814 surveyed agencies have the possibility of having a mandatory unannounced survey, but only 260 are likely to be cited for condition level noncompliance.

TABLE 26

CMS Survey data CY 2010	Total
Active HHAs	11,814
Standard Surveys Completed	3,960
Complaint Surveys Completed	1,446
Standard + Complaint Surveys Completed	5,406
HHAs with ≥1 CoP Citation ..	260

Also, by comparison, in our review of the nursing home data reports, we have found less than 0.3 percent of nursing homes have been subject to the Temporary Management Sanction in 2008 therefore we do not anticipate any major impact on home health provider costs with this sanction in the proposed regulation.

Because implementation of the complex and far-reaching provisions of this proposed rule for CMS would require an infrastructure overhaul with changes to current tracking mechanisms and a nationwide training effort to train surveyors, their supervisors and related CMS personnel, we propose an effective date of one year following a final regulation.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must also conform to the provisions of section 603 of the 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed regulation would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately \$139 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We would incur certain administrative expenses in the course of designing and managing a CMP process. One-time costs are estimated at \$2 million for redesigning certain parts of the survey information system (ASPEN) and ongoing expenses for maintenance and associated modifications of the system are estimated at \$75,000 per year. In addition, we would incur expenses for training Federal and State surveyors, developing and publishing the necessary training and instruction documents and procedures, and tracking and reporting of CMP data. We

estimate one 6 hour webinar training and trouble-shooting session per year involving approximately 302 surveyor and ancillary State and Federal personnel (1812 person-hours) and 190 hours for training development and design. We also estimate 104 hours per year in trouble-shooting and responding to questions. The total combined person hours of 2106 would cost \$299,052 annually. We also estimate ongoing CMS costs for managing the collection and disbursement of CMPs to require about 260 person hours per year or approximately \$36,920. The grand total amounts to \$2 million in onetime expenses and approximately \$335,972 in annual operating costs. The provisions in this proposed rule related to survey protocols have already been incorporated into long standing CMS survey policy, implemented in the years after 1987 and most recently revised in 2011. We project that aggregate Medicare and Medicaid home health survey costs in FY 2013 and FY 2014 would be \$39.9 million and \$45.7 million, respectively. Assuming a standard State Medicaid obligation of 37 percent of the total, the Medicaid share would amount to \$14.7 million and \$16.9 million, respectively. The cost of surveys is treated as a Medicaid administrative cost, reimbursable at the professional staff rate of 75 percent. At this rate the net State Medicaid costs incurred in FYs 2013 and 2014 would be approximately \$3.7 million and \$4.2 million, respectively, spread out across all States and territories.

G. Accounting Statement and Table

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 27, we have prepared an accounting statement showing the classification of the transfers associated with the provisions of this proposed rule. This table provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this proposed rule.

TABLE 27—ACCOUNTING STATEMENT

Category	Transfers
Classification of Estimated Transfers, from the CY 2012 HH PPS to the CY 2013 HH PPS	
Annualized Monetized Transfers	— \$20 million
From Whom to Whom?	Federal Government to HH providers.

TABLE 27—ACCOUNTING STATEMENT—Continued

Federal Medicaid HH Survey and Certification Costs	FYs 2013 to FY 2014	
Category	Transfers	
	Units Discount Rate	
	7%	3%
Classification of Estimated Transfers Relating to the Medicare and Medicaid Home Health Survey and Certification Costs, FYs 2013 to 2014		
Annualized Monetized Transfers	\$11.9 Million	\$11.9 Million.
From Whom to Whom?	Federal Government to Medicaid HH Survey Agencies.	
State Medicaid HH Survey and Certification Costs	FYs 2013 to FY 2014	
Category	Transfers	
	Units Discount Rate	
	7%	3%
Annualized Monetized Transfers	\$3.9 Million	\$3.9 Million.
From Whom to Whom?	State Governments to Medicaid HH Survey Agencies.	
Medicare HH Survey and Certification Costs	FYs 2013 to FY 2014	
Category	Transfers	
	Units Discount Rate	
	7%	3%
Annualized Monetized Transfers	–\$15.8 Million	–\$15.8 Million.
From Whom to Whom?	Federal Government to Medicare HH Survey Agencies.	

H. Conclusion

In conclusion, we estimate that the net impact of the proposals in this rule is approximately \$20 million in CY 2013 savings. The –\$20 million impact to the proposed CY 2013 HH PPS reflects the distributional effects of an updated wage index (\$70 million decrease), the 1.5 percent home health payment update (\$300 million increase), and a 1.32 percent case-mix adjustment applicable to the national standardized 60-day episode rates (\$250 million decrease). This analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis. In addition, this proposed rule would provide that State Medicaid programs share in the cost of HHA surveys. The cost ratio would be calculated at 63 percent for the Medicare program and 37 percent for the Medicaid program. The projected HHA survey budget for FY 2013 is \$39.9 million and FY 2014 at \$45.7 million. The anticipated State Medicaid share is \$3.7 million and \$4.2 million respectively (minus Federal match).

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would 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, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Record and reporting requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare reporting and recordkeeping requirements.

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

PART 409—HOSPITAL INSURANCE BENEFITS

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

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

2. Section 409.44 is amended by revising paragraphs (c)(2)(i)(C)(2), (c)(2)(i)(D)(2), (c)(2)(i)(E) introductory text, and (c)(2)(i)(E)(1) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

- (c) * * *
- (2) * * *
- (i) * * *
- (C) * * *

(2) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide all of the therapy services and functionally reassess the patient in accordance with paragraph (c)(2)(i)(A) of this section during the visit associated with that discipline which is scheduled to occur after the 10th therapy visit but no later than the 13th therapy visit per the plan of care.

(D) * * *

(2) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide all of the therapy services and functionally reassess the patient in accordance with paragraph (c)(2)(i)(A) of this section during the visit associated with that discipline which is scheduled to occur after the 16th therapy visit but no later than the 19th therapy visit per the plan of care.

(E) As specified in paragraphs (c)(2)(i)(A), (B), (C), and (D) of this section, therapy visits for the therapy discipline(s) not in compliance with these policies will not be covered until the following conditions are met:

(1) The qualified therapist has completed the reassessment and objective measurement of the effectiveness of the therapy as it relates to the therapy goals. As long as paragraphs (c)(2)(i)(E)(2) and (c)(2)(i)(E)(3) of this section are met, therapy coverage resumes with the completed reassessment therapy visit.

* * * * *

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 1395(hh)).

4. Section 424.22 is amended by—

A. Revising paragraph (a)(1)(v) introductory text.

B. Redesignating paragraphs (a)(1)(v)(A), (a)(1)(v)(B), (a)(1)(v)(C), and (a)(1)(v)(D) as paragraphs (a)(1)(v)(C), (a)(1)(v)(D), (a)(1)(v)(E), and (a)(1)(v)(F), respectively.

C. Adding new paragraphs (a)(1)(v)(A) and (a)(1)(v)(B).

D. Revising newly redesignated paragraphs (a)(1)(v)(C) and (a)(1)(v)(F).

The revisions and additions read as follows:

§ 424.22 Requirements for home health services.

* * * * *

- (a) * * *
- (1) * * *

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has 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 by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter, respectively.

(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 documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled and dated and the certification must be signed by the certifying physician.

(C) In cases where the face-to-face encounter is performed by an acute or post-acute care physician who cared for the patient in an acute or post-acute care facility or by a non-physician practitioner in collaboration with or under the supervision of such an acute or post-acute care physician who is not directly communicating to the certifying physician the clinical findings (i.e., the patient's homebound status and need for intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter), the acute or post-acute care physician must communicate the clinical findings of that face-to-face encounter to the certifying physician. In all other cases where a non-physician practitioner performs the face-to-face encounter, the nonphysician practitioner must communicate the clinical findings of that face-to-face patient encounter to the certifying physician.

* * * * *

(F) The physician responsible for certifying the patient for home care must document the face-to-face encounter on the certification itself, or as an addendum to the certification (as described in paragraph (a)(1)(v) of this section), that the condition for which the patient was being treated in the face-to-face patient encounter is related to the primary reason the patient requires home health services, and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter respectively. The documentation must be clearly titled and dated and the documentation must be signed by the certifying physician.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

5. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302)

6. Section 431.610 is amended by revising paragraph (g) introductory text to read as follows:

§ 431.610 Relations with standard-setting and survey agencies.

* * * * *

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying NFs, HHAs, and ICF-IIDs, the survey agency designated under paragraph (e) of this section will—

* * * * *

PART 484—HOME HEALTH SERVICES

7. 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)).

8. Section 484.250 is amended by adding paragraph (c)(3) to read as follows:

§ 484.250 Patient assessment data.

* * * * *

(c) * * *

(3) Approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities, including allowing CMS and its HHCAHPS program team to perform site visits at the vendors' company locations.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

9. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111-148)

10. Section 488.2 is amended by adding the following statutory basis in numerical order as follows:

§ 488.2 Statutory basis.

* * * * *

1861(m)—Requirements for home health services.

1861(o)—Requirements for home health agencies.

* * * * *

1891—Conditions of participation for home health agencies; home health quality.

* * * * *

11. Section 488.3 is amended by revising paragraph (a)(1) to read as follows:

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) * * *

(1) Meet the applicable statutory definition in sections 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, 1891, or 1919 of the Act.

* * * * *

12. Section 488.26 is amended by revising paragraphs (c)(2) and (e) to read as follows:

§ 488.26 Determining compliance.

* * * * *

(c) * * *

(2) The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients.

* * * * *

(e) The State survey agency must ensure that a facility's or agency's actual provision of care and services to residents and patients and the effects of that care on such residents and patients are assessed in a systematic manner.

13. The section heading for § 488.28 is revised to read as follows:

§ 488.28 Providers or suppliers, other than SNFs, NFs, and HHAs with deficiencies.

* * * * *

14. A new subpart I is added to read as follows:

Subpart I—Survey and Certification of Home Health Agencies

Sec.

488.700	Basis and scope.
488.705	Definitions.
488.710	Standard surveys.
488.715	Partial extended surveys.
488.720	Extended surveys.
488.725	Unannounced surveys.
488.730	Survey frequency and content.
488.735	Surveyor qualifications.
488.740	Certification of compliance or noncompliance.
488.745	Informal Dispute Resolution (IDR).

Subpart I—Survey and Certification of Home Health Agencies

§ 488.700 Basis and scope.

Section 1891 of the Act establishes requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation.

§ 488.705 Definitions.

As used in this subpart—
Abbreviated standard survey means a focused survey other than a standard survey that gathers information on an HHA's compliance with specific conditions of participation. An abbreviated standard survey may be

based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation.

Complaint survey means a survey that is conducted to investigate specific allegations of noncompliance.

Condition-level deficiency means noncompliance as described in § 488.24 of this part.

Deficiency is a violation of the Act and regulations contained in part 484, subparts A through C of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Extended survey means a survey that reviews all conditions of participation. It may be conducted at any time but must be conducted when one or more condition-level deficiencies (substandard care) are identified.

Noncompliance means any deficiency found at the condition-level or standard-level.

Partial extended survey means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for HHAs.

Standard survey means a survey conducted in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care.

Substandard care means noncompliance with one or more conditions of participation, including deficiencies which could result in actual or potential harm to patients at an HHA.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.710 Standard surveys.

(a) For each HHA, the survey agency must conduct a standard survey not later than 36 months after the date of the previous standard survey that includes, but is not limited to, all of the following (to the extent practicable):

(1) A case-mix stratified sample of individuals furnished items or services by the HHA.

(2) Visits to the homes of patients, (the purpose of the home visit is to

evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of each patient as reflected in the patient's written plan of care and clinical records), but only with their consent, and, if determined necessary by CMS or the survey team, other forms of communication with patients including telephone calls.

(3) Review of indicators that include the outcomes of quality care and services furnished by the agency as indicated by medical, nursing, and rehabilitative care.

(4) Review of compliance with a select number of regulations most related to high-quality patient care.

(b) The survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that deficiencies exist at an HHA.

§ 488.715 Partial extended surveys.

A partial extended survey is conducted to determine if standard or condition-level deficiencies are present in the conditions of participation not fully examined during the standard survey and there are indications that a more comprehensive review of conditions of participation would determine if a deficient practice exists.

§ 488.720 Extended surveys.

(a) *Purpose of survey.* The purpose of an extended survey is:

(1) To review and identify the policies and procedures that caused an HHA to furnish substandard care.

(2) To determine whether the HHA is in compliance with *all* of the conditions of participation.

(b) *Timing and basis for survey.* An extended survey must be conducted not later than 14 calendar days after completion of a standard survey which found that a HHA had furnished substandard care.

§ 488.725 Unannounced surveys.

(a) *Basic rule.* All HHA surveys must be unannounced and conducted with procedures and scheduling that renders the onsite surveys as unpredictable in their timing as possible.

(b) *State survey agency's scheduling and surveying procedures.* CMS reviews each survey agency's scheduling and surveying procedures and practices to assure that the survey agency has taken all reasonable steps to avoid giving notice of a survey through the scheduling procedures and conduct of the surveys.

(c) *Civil money penalties.* Any individual who notifies an HHA, or

causes an HHA to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed \$2,000.

§ 488.730 Survey frequency and content.

(a) *Basic period.* Each HHA must be surveyed not later than 36 months after the last day of the previous standard survey. Additionally, a survey may be conducted as frequently as necessary to—

(1) Assure the delivery of quality home health services by determining whether an HHA complies with the Act and conditions of participation; and

(2) Confirm that the HHA has corrected deficiencies that were previously cited.

(b) *Change in HHA information.* A standard survey or an abbreviated standard survey may be conducted within 2 months of a change in any of the following:

(1) Ownership;

(2) Administration; or

(3) Management of the HHA.

(c) *Complaints.* A standard survey, or abbreviated standard survey—

(1) Must be conducted of an HHA within 2 months of when a significant number of complaints against the HHA are reported to CMS, the State, the State or local agency responsible for maintaining a toll-free hotline and investigative unit, or any other appropriate Federal, State, or local agency; or

(2) As otherwise required to determine compliance with the conditions of participation such as the investigation of a complaint.

§ 488.735 Surveyor qualifications.

(a) *Minimum qualifications.* Surveys must be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any State or Federal surveyor may serve on an HHA survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites. All surveyors must follow the principles set forth in § 488.24 through § 488.28 according to CMS policies and procedures for determining compliance with the conditions of participation.

(b) *Disqualifications.* Any of the following circumstances disqualifies a surveyor from surveying a particular agency:

(1) The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as:

(i) A direct employee;

(ii) An employment agency staff at the agency; or

(iii) An officer, consultant, or agent for the agency to be surveyed concerning compliance with conditions of participation specified in or pursuant to sections 1861(o) or 1891(a) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.

(3) The surveyor has a family member who has a relationship with the HHA to be surveyed.

(4) The surveyor has an immediate family member who is a patient of the HHA to be surveyed.

§ 488.740 Certification of compliance or noncompliance.

Rules to be followed for certification, documentation of findings, periodic review of compliance and approval, certification of noncompliance, and determining compliance of HHAs are set forth, respectively, in § 488.12, § 488.18, § 488.20, § 488.24, and § 488.26.

§ 488.745 Informal Dispute Resolution (IDR).

(a) *Opportunity to refute survey findings.* Upon the provider's receipt of an official statement of deficiencies, HHAs are afforded the option to request an informal opportunity to dispute condition-level survey findings.

(b) *Failure to conduct IDR timely.*

Failure of CMS or the State, as appropriate, to complete IDR shall not delay the effective date of any enforcement action.

(c) *Revised Statement of Deficiencies as a result of IDR.* If any findings are revised or removed by CMS or the State based on IDR, the official statement of deficiencies is revised accordingly and any enforcement actions imposed solely as a result of those cited deficiencies are adjusted accordingly.

(d) *Notification.* When the survey findings indicate a condition-level deficiency, CMS or the State, as appropriate, must provide the agency with written notification of the opportunity for participating in an IDR process at the time the official statement of deficiencies is issued. The request for IDR must be submitted in writing to the State or CMS, should include the specific deficiencies that are disputed, and should be made within the same 10 calendar day period that the HHA has for submitting an acceptable plan of correction.

15. A new subpart J is added to read as follows:

Subpart J—Alternative Sanctions for Home Health Agencies With Deficiencies

Sec.

488.800 Statutory basis.

488.805 Definitions.

488.810 General provisions.

- 488.815 Factors to be considered in selecting sanctions.
- 488.820 Available sanctions.
- 488.825 Action when deficiencies pose immediate jeopardy.
- 488.830 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.
- 488.835 Temporary management.
- 488.840 Suspension of payment for all new patient admissions and new payment episodes.
- 488.845 Civil money penalties.
- 488.850 Directed plan of correction.
- 488.855 Directed in-service training.
- 488.860 Continuation of payments to an HHA with deficiencies.
- 488.865 Termination of provider agreement.

Subpart J—Alternative Sanctions for Home Health Agencies With Deficiencies

§ 488.800 Statutory basis.

Section 1891(e) through (f) of the Act authorizes the Secretary to take actions to remove and correct deficiencies in an HHA through an alternative sanction or termination or both. Furthermore, this section specifies that these sanctions are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.805 Definitions.

As used in this subpart—

Directed plan of correction means CMS or the temporary manager (with CMS/SA approval) may direct the HHA to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the HHA on or after the effective date of a suspension of payment sanction or new payment episode of an existing patient on or after the effective date of a suspension of payment sanction.

Per instance means a single event of noncompliance identified and corrected through a survey, for which the statute authorizes CMS to impose a sanction;

Plan of correction means a plan developed by the HHA and approved by CMS that is the HHA's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a standard or condition-level deficiency that is cited on the current survey and is substantially the same as, or similar to,

a finding of noncompliance issued on the most recent previous survey.

Temporary management means the temporary appointment by CMS or a CMS authorized agent of a substitute manager or administrator based upon qualifications described in § 484.4 and § 484.14(c), under the direction of the HHA's governing body who has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA to correct deficiencies identified in the HHA's operation.

§ 488.810 General provisions.

(a) *Purpose of sanctions.* The purpose of sanctions is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of an HHA.

(b) *Basis for imposition of sanctions.* When CMS chooses to apply one or more sanctions specified in § 488.820, the sanctions are applied on the basis of noncompliance with conditions of participation found through surveys and may be based on failure to correct previous deficiency findings as evidenced by repeat deficiencies.

(c) *Number of sanctions.* CMS may apply one or more sanctions for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Extent of sanctions imposed.* When CMS imposes a sanction, the sanction applies to the parent HHA and its respective branch offices. The sanctions imposed on a parent and/or its respective branches do not apply to the associated subunit.

(e) *Plan of correction requirement.* Regardless of which sanction is applied, a non-compliant HHA must submit a plan of correction for approval by CMS.

(f) *Notification requirements—*(1) *Notice.* CMS provides written notification to the HHA of the intent to impose the sanction.

(2) *Date of enforcement action.* The notice periods specified in § 488.825(b) and § 488.830(b) begin the day after the HHA receives the notice.

(g) *Appeals.* (1) The provisions of part 498 of this chapter apply when the HHA requests a hearing on a determination of noncompliance leading to the imposition of a sanction, including termination of the provider agreement.

(2) A pending hearing does not delay the effective date of a sanction, including termination, against an HHA. Sanctions continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.815 Factors to be considered in selecting sanctions.

CMS bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the HHA's overall compliance history and any history of repeat deficiencies at either the parent or branch location.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the HHA is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.820 Available sanctions.

In addition to termination of the provider agreement, the following alternative sanctions are available:

(a) Civil money penalties.

(b) Suspension of payment for all new admissions and new payment episodes.

(c) Temporary management of the HHA.

(d) Directed plan of correction, as set out at § 488.850.

(e) Directed in-service training, as set out at § 488.855.

§ 488.825 Action when deficiencies pose immediate jeopardy.

(a) *Immediate jeopardy.* If there is immediate jeopardy to the HHA's patient health or safety—

(1) CMS immediately terminates the HHA provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the HHA provider agreement no later than 23 days from the last day of the survey, if the immediate jeopardy has not been removed by the HHA.

(3) In addition to a termination, CMS may impose one or more alternative sanctions, as appropriate.

(b) *2-day notice.* Except for civil money penalties, for all sanctions specified in § 488.820 that are imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action.

(c) *Transfer of care.* An HHA, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local HHA within 30

days of termination. The State must assist the HHA in the safe and orderly transfer of care and services for the patients to another local HHA.

§ 488.830 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) *Noncompliance.* If the HHA is no longer in compliance with the conditions of participation, either because the deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, or because the HHA has repeat noncompliance with standard-level deficiencies or repeat condition-level deficiencies that would lead to noncompliance based on the HHA's failure to correct and sustain compliance as described in their proposed plan of correction with the condition as set forth in part 484 of this chapter, CMS will:

(1) Terminate the HHA's provider agreement; or

(2) In addition to, or as an alternative to termination for a period not to exceed six months, impose one or more alternative sanctions set forth in § 488.820(a) through (f) of this subpart.

(b) *15-day notice.* Except for civil money penalties, for all sanctions specified in § 488.820 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.810(f).

(c) *Not meeting criteria for continuation of payment.* If an HHA does not meet the criteria for continuation of payment under § 488.860(a), CMS will terminate the HHA's provider agreement in accordance with § 488.865.

(d) *Termination time frame when there is no immediate jeopardy.* CMS terminates an HHA within 6 months of the last day of the survey, if the HHA is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) *Transfer of care.* An HHA, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local HHA within 30 days of termination. The State must assist the HHA in the safe and orderly transfer of care and services for the patients to another local HHA.

§ 488.835 Temporary management.

(a) *Application.* (1) CMS may impose temporary management of an HHA if it determines that an HHA has a condition-level deficiency(ies) and CMS

determines that management limitations or the deficiencies are likely to impair the HHA's ability to correct deficiencies and return the HHA to full compliance with the conditions of participation within the timeframe required.

(2) [Reserved]

(b) *Procedures.* (1) CMS notifies the HHA that a temporary manager is being appointed.

(2) If the HHA fails to relinquish authority and control to the temporary manager, CMS terminates the HHA's provider agreement in accordance with § 488.865.

(c) *Duration and effect of sanction.* Temporary management continues until—

(1) CMS determines that the HHA has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation;

(2) CMS terminates the provider agreement; or

(3) The HHA reassumes management control without CMS approval. In such case, it would be a failure to relinquish authority and control to temporary management and CMS initiates termination of the provider agreement and may impose additional sanctions. Temporary management will not exceed a period of six months from the date of the survey identifying noncompliance.

(d) *Payment of salary.* (1) The temporary manager's salary—

(i) Is paid directly by the HHA while the temporary manager is assigned to that HHA; and

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the HHA's geographic area (prevailing salary based on the Geographic Guide by the Department of Labor (BLS Wage Data by Area and Occupation);

(B) Any additional costs that would have reasonably been incurred by the HHA if such person had been in an employment relationship; and

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) An HHA's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

(3) The costs of a temporary manager is not an allowable item on a cost report, as described in § 488.30.

§ 488.840 Suspension of payment for all new patient admissions and new payment episodes.

(a) *Application.* (1) CMS may suspend payment for all new admissions and new payment episodes if an HHA is found to have condition-level deficiencies, regardless of whether those deficiencies pose immediate jeopardy.

(2) CMS will consider this sanction for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) *Procedures—(1) Notices.* (i) Before suspending payments for new admissions or new payment episodes, CMS provides the HHA notice of the suspension of payment for all new admissions and all new payment episodes as set forth in § 488.810(f). The CMS notice of suspension will include the nature of the non-compliance; the effective date of the sanction; and the right to appeal the determination leading to the sanction.

(ii) The HHA may not charge a newly admitted HHA patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the HHA can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) *Restriction.* (i) Suspension of payment for all new admissions and new payment episodes sanction may be imposed anytime an HHA is found to be out of substantial compliance.

(ii) Suspension of payment for patients with new admissions or patients with new payment episodes will remain in place until CMS determines that the HHA has achieved substantial compliance or is involuntarily terminated with the conditions of participation, as determined by CMS.

(3) *Resumption of payments.*

Payments to the HHA resume prospectively on the date that CMS determines that the HHA has achieved substantial compliance with the conditions of participation.

(c) *Duration and effect of sanction.* This sanction ends when—

(1) CMS determines that the HHA is in substantial compliance with all of the conditions of participation; or

(2) When the HHA is terminated or CMS determines that the HHA is not in compliance with the conditions of participation at a maximum of 6 months from the date noncompliance was determined.

§ 488.845 Civil money penalties.

(a) *Application.* (1) CMS may impose a civil money penalty against an HHA for either the number of days the HHA is not in compliance with one or more conditions of participation or for each instance that an HHA is not in compliance, regardless of whether the HHA's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance CMP may not be imposed simultaneously for the same deficiency.

(b) *Amount of penalty.* (1) *Factors considered.* CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.815.

(ii) The size of an agency and its resources.

(iii) The availability of other HHAs within a region.

(iv) Accurate and credible resources, such as PECOS, Medicare cost reports and Medicare/Medicaid claims information that provide information on the operation and resources of the HHA.

(v) Evidence that the HHA has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) *Adjustments to penalties.* Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a HHA's inability or unwillingness to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA is not yet in full compliance with the conditions of participation.

(iii) No penalty assessment shall exceed \$10,000 for each day of noncompliance.

(3) *Upper range of penalty.* Penalties in the upper range of \$8,500 to \$10,000 per day of noncompliance are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range will continue until compliance

can be determined based on a revisit survey.

(4) *Middle range of penalty.* Penalties in the range of \$3,500–\$8,500 per day of noncompliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes.

(i) \$8,500 per day for a repeat deficiency or deficiencies.

(ii) \$2500 to \$5,000 per day for other deficiencies.

(5) *Lower range of penalty.* Penalties within this range are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

(i) \$4,000 per day for a repeat deficiency or deficiencies.

(ii) \$500 to \$3,000 per day for other deficiencies.

(6) *Per instance penalty.* Penalties imposed per instance of noncompliance may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of \$1,000 to \$10,000 per instance, not to exceed \$10,000 each day of noncompliance.

(7) *Decreased penalty amounts.* If the immediate jeopardy situation is removed, but condition-level noncompliance continues, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) *Increased penalty amounts.* (i) In accordance with paragraph (b)(2) of this section, CMS will increase the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or

uncorrected deficiencies from a prior survey.

(c) *Procedures—(1) Notice of intent.* CMS provides the HHA with written notice of the intent to impose a civil money penalty. The notice includes the amount of the CMP being imposed, the basis for such imposition, and the proposed effective date of the sanction.

(2) *Appeals—(i) Appeals procedures.* An HHA may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) *Waiver of a hearing.* An HHA may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty. If an HHA timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 days of the HHAs agreeing in writing to waive the hearing. If the HHA does not waive its right to a hearing in accordance to the procedures specified in this section, the civil money penalty is not reduced by 35 percent.

(d) *Accrual and duration of penalty.*

(1) The per day civil money penalty may start accruing as early as the beginning of the date of the survey that determines that the HHA was out of compliance, as determined by CMS.

(2) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of \$10,000 per day per HHA. A penalty that is imposed per day and per instance of noncompliance may not be imposed simultaneously.

(3) *Duration of per day penalty when there is immediate jeopardy.* (i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the HHA achieves substantial compliance, whichever occurs first.

(4) *Duration of penalty when there is no immediate jeopardy.* (i) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the HHA has not achieved compliance with the conditions of participation, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the HHA agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

(e) *Computation and notice of total penalty amount.* (1) When a civil money penalty is imposed on a per day basis and the HHA achieves compliance with the conditions of participation as determined by a revisit survey, CMS sends a final notice to the HHA containing all of the following information:

(i) The amount of penalty assessed per day.

(ii) The total number of days of noncompliance.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(4) of this section.

(2) When a civil money penalty is imposed for per instance of noncompliance, CMS sends a notice to the HHA containing all of the following information:

(i) The amount of the penalty that was assessed.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of an HHA for which the provider agreement has been involuntarily terminated and for which a civil money penalty was imposed on a per day basis, CMS sends this penalty information after one of the following actions has occurred:

(i) Final administrative decision is made.

(ii) The HHA has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and CMS has not received a hearing request from the HHA.

(f) *Due date for payment of penalty.* A penalty is due and payable 15 days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 days:

(i) After a final administrative decision when the HHA achieves substantial compliance before the final decision or the effective date of termination before final decision,

(ii) After the time to appeal has expired and the HHA does not appeal or fails to timely appeal the initial determination,

(iii) After CMS receives a written request from the HHA requesting to waive its right to appeal the determinations that led to the imposition of a sanction,

(iv) After substantial compliance is achieved, or

(v) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If an HHA waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS will apply a 35 percent reduction to the CMP amount when:

(i) The HHA achieved compliance with the conditions of participation before CMS received the written waiver of hearing; or

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the HHA.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) *Penalties collected by CMS—(1) Disbursement of CMPs.* Civil money penalties and any corresponding interest collected by CMS from Medicare and Medicaid participating HHAs are disbursed in proportion to average dollars spent by Medicare and Medicaid at the national level based on MSIS and HHA PPS data for a three year fiscal period.

(i) Based on expenditures for the FY 2007–2009 period, the initial proportions to be disbursed are 63 percent returned to the U.S. Treasury and 37 percent returned to the State Medicaid agency.

(ii) Beginning one year after the effective date of this section, CMS shall annually update these proportions based on the most recent 3-year fiscal period, prior to the year in which the CMP is imposed, for which CMS determines that the relevant data are essentially complete.

(iii) The portion corresponding to the Medicare is returned to the U.S. Department of Treasury as miscellaneous receipts.

(iv) The portion corresponding to the Medicaid payments is returned to the State Medicaid agency.

(2) Penalties may not be used for Survey and Certification operations nor as the State's Medicaid non-Federal medical assistance or administrative match.

§ 488.850 Directed plan of correction.

(a) *Application.* CMS may impose a directed plan of correction when an HHA:

(1) Has one or more deficiencies that warrant directing the HHA to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) *Procedures.* (1) Before imposing this sanction, CMS provides the HHA notice of the impending sanction.

(2) CMS or the temporary manager (with CMS approval) may direct the HHA to take corrective action to achieve specific outcomes within specific timeframes.

(c) *Duration and effect of sanction.* If the HHA fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, CMS:

(1) May impose one or more other sanctions set forth in § 488.820; or

(2) Terminates the provider agreement.

§ 488.855 Directed in-service training.

(a) *Application.* CMS may require the staff of an HHA to attend in-service training program(s) if CMS determines that—

(1) The HHA has deficiencies that indicate noncompliance;

(2) Education is likely to correct the deficiencies; and

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare Home Health Providers, or as deemed acceptable by CMS and/or the State (by review of a copy of curriculum vitas and/or resumes/ references to determine the educator's qualifications).

(b) *Procedures.* (1) *Action following training.* After the HHA staff has received in-service training, if the HHA has not achieved compliance, CMS may impose one or more other sanctions specified in § 488.820.

(2) *Payment.* The HHA pays for the directed in-service training for its staff.

§ 488.860 Continuation of payments to an HHA with deficiencies.

(a) *Continued payments.* CMS may continue payments to an HHA with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) *Criteria.* CMS may continue payments to an HHA not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) The HHA has been imposed an alternative sanction or sanctions and termination has not been imposed.

(ii) The HHA has submitted a plan of correction approved by CMS.

(iii) The HHA agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS may terminate the HHA's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments for new admissions.* If termination is imposed, either on its own or in addition to an alternative sanction or sanctions, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the HHA will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) *Failure to achieve compliance with the conditions of participation.* If the HHA does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS will terminate the provider agreement of the HHA in accordance with § 488.865 of this part.

§ 488.865 Termination of provider agreement.

(a) *Effect of termination by CMS.* Termination of the provider agreement ends—

(1) Payment to the HHA; and

(2) Any alternative sanction(s).

(b) *Basis for termination.* CMS terminates an HHA's provider agreement under any one of the following conditions—

(1) The HHA is not in compliance with the conditions of participation.

(2) The HHA fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The HHA fails to relinquish control to the temporary manager, if that sanction is imposed by CMS.

(4) The HHA fails to meet the eligibility criteria for continuation of payment as set forth in § 488.860(a)(1).

(c) *Notice.* CMS notifies the HHA and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) *Procedures for termination.* CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) *Appeal.* An HHA may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

16. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1128I and 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1351i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

17. Section 489.53 is amended by adding paragraphs (a)(17) and (d)(2)(iii) to read as follows:

§ 489.53 Termination by CMS.

(a) * * *

(17) In the case of an HHA, it failed to correct any deficiencies within the required time frame.

* * * * *

(d) * * *

(2) * * *

(iii) *Home health agencies (HHAs).*

For an HHA with deficiencies that pose immediate jeopardy to the health and safety of patients, CMS gives notice to the HHA at least 2 days before the effective date of termination of the provider agreement.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

18. The authority citation for part 498 continues to read as follows:

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

19. Section 498.3 is amended by revising paragraphs (b)(13), (b)(14) introductory text, (b)(14)(i), and (d)(10) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at § 498.3(d)(12) for SNFs, NFs, and HHAs the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406 or § 488.740 of this chapter, but not the determination as to which sanction was imposed. The scope of review on the imposition of a civil money penalty is specified in § 488.438(e) of this chapter.

(14) The level of noncompliance found by CMS in a SNF, NF, or HHA but only if a successful challenge on this issue would affect—

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter); or

* * * * *

(d) * * *

(10) For a SNF, NF, or HHA—

(i) The finding that the provider's deficiencies pose immediate jeopardy to the health or safety of the residents or patients;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by CMS as to the provider's level of noncompliance; and

(iii) For SNFs and NFs, the imposition of State monitoring.

* * * * *

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: June 27, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2012.

Kathleen Sebelius,
Secretary.

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