DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1358–F]

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: Final rule.

SUMMARY: This final rule updates 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), the non-routine medical supplies (NRS) conversion factor, and outlier payments under the Medicare prospective payment system for home health agencies effective January 1, 2013. This rule also establishes requirements for the Home Health and Hospice quality reporting programs. This final rule will also establish requirements for unannounced, standard and extended surveys of home health agencies (HHAs) and sets 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 an HHA achieves compliance with the HHA Conditions of Participation (CoPs) or until the HHA's provider agreement is terminated.

DATES: This rule is effective on January 1, 2013, except for:

a. The amendments to 42 CFR 488.2, 488.3, 488.26, and 488.28, and the additions of 42 CFR part 488, subparts I and J, which are effective July 1, 2013 (except that § 488.745, § 488.840 and § 488.845 are effective July 1, 2014).

b. The amendments to 42 CFR 489.53 and 498.3, which are effective July 1, 2013.

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SUPPLEMENTARY INFORMATION:

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Acronyms

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

ACH LOS Acute Care Hospital Length of Stay
ADL Activities of Daily Living
APU Annual Payment Update
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
CAD Coronary Artery Disease
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CASPER Certification And Survey Provider Enhanced Reports
CHF Congestive Heart Failure
CMI Case-Mix Index
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
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCIS Health Care Information System
HH Home Health
HHABN Home Health Advance Beneficiary Notice
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 updates 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 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 final 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 rebased and revised market basket described in section III.C.1 of this rule. This rule discusses the nominal case-mix growth adjustment, policy changes regarding therapy reassessments and face-to-face encounter requirements, grouper enhancements, and requirements concerning the home health and hospice quality reporting programs. We also provide an update on the transition plan for ICD–10 and the home health study concerning home health care access. Lastly, this rule establishes alternative sanctions, in lieu of termination, for HHAs found not to be in compliance with Medicare Conditions of Participation.

C. Summary of Costs and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total costs	Total benefits	Transfers
CY 2013 HH PPS payment rate update.	N/A	The benefits of this final 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.	The overall economic impact of this final rule is an estimated $10 million in decreased payments to HHAs.
HHA Survey Requirements and Alternative (or Intermediate) Sanctions That May be Imposed when HHAs are Out of Compliance with federal Requirements.	The components of the rule, which address survey requirements, codify current Survey and Certification policies and do not represent new costs. We estimate that the costs associated with Informal Dispute Resolution (IDR) will not be significantly greater than current actions related to termination actions. We estimate a onetime $2 million expense for system modifications to monitor Civil Money Penalties and annual operating expenses of $410,972 to maintain the system and provide surveyor training.	The benefits of this rule include establishing alternative (or intermediate) sanctions that may be imposed when HHAs are out of compliance with federal requirements, increasing provider participation related to survey findings via the IDR, and incentives for HHAs to maintain or regain compliance with the HHA Conditions of Participation through measures other than termination.	N/A.

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

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

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

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. 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 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. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532) we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

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.

Following up on our commitment to further study case-mix change over time and the methodology used to determine real versus nominal case-mix change, we procured an independent review of our methodology by a team at Harvard University, lead by Dr. David Grabowski. That review led to a slight enhancement of the case-mix model, but otherwise confirmed the model's accuracy (please see the report located at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HHPPS_HHAcasemixgrowthFinalReport.pdf*).

III. Summary of Proposed Provisions and Analysis of and Responses to Public Comments

A. Case-Mix Measurement

As described in the CY 2013 HH PPS proposed rule issued in the July 13, 2012 **Federal Register** (77 FR 41548) and in section II.B of this rule, we have implemented payment reductions to the national standardized 60-day episode payment rates over the past 5 years to account for nominal case-mix growth, that is, case-mix growth unrelated to changes in patient acuity.

When including the latest data available, data from 2000 to 2010, we determined that there was a 20.08 percent nominal case-mix change during that time period. 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 estimated 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 solicited comments on that proposal. However for CY 2013, we proposed 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. We note that 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 real and nominal case-mix change and make updates as appropriate. We will consider any and all analyses as it continues to address the issue of the increase in nominal case-mix in future rulemaking.

The following is a summary of the comments we received regarding the case-mix measurement proposal.

Comment: One commenter stated that the payment reductions for nominal case-mix growth are based on the unsubstantiated assertion that HHAs have intentionally ''gamed the system'' by coding their patients at a higher clinical severity level in order to receive higher payments.

Response: As we have stated in previous regulations, we believe nominal coding change results mostly from changed coding practices, including improved understanding of the ICD–9 coding system, more comprehensive coding, changes in the interpretation of various items on the OASIS and in formal OASIS definitions, and other evolving measurement issues. Our view of the causes of nominal coding change does not emphasize the idea that HHAs or clinicians in general ''gamed the system.'' However, since our goal is to pay increased costs associated with real changes in patient severity, and nominal coding change does not demonstrate that underlying changes in patient severity occurred, we believe it is necessary to exclude nominal case-mix effects that are unrelated to changes in patient severity.

Comment: Several commenters stated that CMS should not implement across-the-board reductions in payments, but rather apply the reductions only to HHAs that are abusing the system, or upcoding. Commenters stated that the payment reductions penalize agencies where case-mix increases have been less than average. A commenter stated that those agencies with a low average case-mix should be protected from further cuts since the cuts are based on a high case-mix weight. Other commenters stated that across the board cuts do not directly address problems with upcoding. One commenter stated that instead of implementing an across the board cut, CMS should redirect its focus to approaches that target specific practices that have caused the case-mix increase and that these methods should be implemented in conjunction with rebasing.

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

We note that although we have stated in past regulations that a targeted system would be administratively burdensome, the reasons we have just presented go beyond administrative complexity. Certain comments seem to assume that we can use case-mix levels to precisely identify those agencies with inappropriate coding practices. We do not agree that agency-specific case-mix levels can precisely differentiate agencies with inappropriate coding practices from other agencies that are coding appropriately. System wide, case-mix levels have risen over time while data on patient characteristics indicate little change in patient severity over time. That is, the main problem is not the level of case-mix reached over a period of time, but the amount of change in the billed case-mix weights not attributable to underlying changes in actual patient severity. We continue to explore potential changes to the HH PPS which could deter future nominal case-mix growth, such as the recalibration implemented in the CY 2012 final rule, and possible changes in conjunction with rebasing. However, we believe we still need to implement payment reductions to account for nominal case-mix change from the inception of the HH PPS through 2009.

Comment: A commenter stated that across the board cuts appear to be based on high profit margins of agencies that are not committed to serving all patients.

Response: We note that the payment reductions are based on our assessment of real and nominal case-mix growth. High profit margins do not play a role

in our calculations of the payment reductions.

Comment: Commenters recommended that CMS target specific HHAs by reducing case-mix adjustments for HHAs with Medicare margins that are significantly above average for similarly situated HHAs. A commenter cited MedPAC's report of the variation in margins for home health providers and stated that the vast disparity in Medicare margins among HHAs makes across the board payment cuts not only unwarranted and unfair, but also potentially devastating for those whose costs exceed Medicare reimbursement.

Response: Case-mix adjustments are based on changes in real and nominal case-mix over time. Our analyses of coding change among many classifications of agencies, as described in the CY 2012 proposed and final rules, found relatively little difference across provider types in the amount of coding change. An examination of coding change by profitability may have similar results, as profitability may reflect efficiency rather than upcoding. We further note that a classification by profitability would be complicated by the fact that profitability can vary from year to year.

Comment: A commenter stated that applying the 1.32 percent payment reduction would be premature and that CMS should wait to apply the reduction until there are more data to review for 2011 and in particular 2012, where there has been a significant shift in the case-mix away from therapy episodes. The commenter stated that the 2012 recalibration will likely change agency behavior and, in turn, have an effect on the average case-mix weight. The commenter urged CMS to wait to make further payment reductions until it can analyze complete data sets from 2011 and 2012.

Response: As we have stated in previous rulemaking since the start of the HH PPS, we continue to use data samples that represent a 2-year lag in service dates relative to the year in which we conduct the analysis. We note that while we analyzed 2010 data, which showed that we would need to implement a 2.18 percent reduction to account for nominal case-mix growth through 2010, we only proposed to implement a 1.32 percent reduction which would account for nominal case-mix growth from 2000 to 2009. We agree with the commenter that the recalibration in CY 2012 may have an effect on the average case-mix weight and we note that this has been taken into account when considering the 1.32 percent reduction versus than the 2.18 percent reduction. We would like to point out that the 1.32 percent payment reduction was finalized in the CY 2012 rule and we believe that with the steady increases in nominal case-mix growth over the years, there is a need to implement a payment reduction to account for this growth. We plan to continue to analyze data as it becomes available and propose payment adjustments accordingly.

Comment: A commenter stated that CMS should use the most current metrics in analyzing case-mix growth and that they were willing to help with this effort.

Response: Currently, we use claims data matched to OASIS assessments and Part A information, as well as HCC data, in the analysis of real and nominal case-mix growth. The commenter did not specify what they consider to be the most current metrics. However, we will continue to solicit concrete suggestions for other metrics that can be incorporated in our analysis.

Comment: A commenter stated that CMS proposed a 1.32 percent decrease in payments to account for nominal case-mix growth from 2000 to 2010.

Response: We would like to clarify that the 1.32 percent decrease in payments was finalized in the CY 2012 final rule in order to account for nominal case-mix growth from 2000 to 2009. Our updated analysis shows that in order to account for nominal case-mix growth from 2000 to 2010, we would need to implement a 2.18 percent reduction to payments for CY 2013. Therefore, for this rule, we are finalizing the 1.32 percent case-mix adjustment.

Comment: A commenter stated that the proposed national standardized 60-day episode payment rate has only increased by a total of 1 percent in 12 years.

Response: While the national standardized 60-day episode payment rate has not increased substantially in recent years, overall Medicare HH expenditures increased from $10.1 billion in 2003 to $18.6 billion in 2011, an increase of 84 percent, and the number of HH users increased 30 percent during the same time period. However, payment for an episode does not solely rely on the national standardized 60-day episode base payment rate. One must take into account the average case-mix weight when looking at HH PPS payments. The average case-mix weight has continually increased over the years while our analysis shows relatively lower real case-mix growth. The average case-mix weight in 2000 was 1.0959 while the average case-mix weight in 2009 was 1.3435, a total case-mix change from 2000 to 2009 of 22.59 percent ((1.3435 − 1.0959)/1.0959). When taking into account the 15.76 percent of total case-mix change estimated as real from 2000 to 2009, the nominal case-mix change measure is 19.03 percent (0.2259 * (1 − 0.1576) = 0.1903) from 2000 to 2009. Therefore, we believe a payment reduction is necessary to align payments with the real case-mix growth we have observed.

Comment: A commenter stated that a further payment reduction is unwarranted especially with rebasing next year.

Response: We are finalizing a 1.32 percent payment reduction to the CY 2013 national standardized 60-day episode base payment rate intended to account for increases in billed case-mix weights, resulting in overpayments, that have occurred between 2000 and 2009, above and beyond the real change in case-mix. Since our analysis indicates that margins will remain adequate, and our analysis for purposes of rebasing is still in process, we see no reason to defer the nominal case-mix adjustment in this rule.

Comment: A commenter recommended that CMS find alternative ways to account for nominal case-mix growth that do not impose payment reductions to the HH PPS.

Response: Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions for nominal case-mix growth by applying reductions to the base payment. We continue to explore ways to prevent future nominal case-mix growth and we welcome any suggestions.

Comment: Some commenters stated that CMS should increase its program integrity efforts to combat fraud, waste, and abuse. Other commenters stated that CMS should eliminate the proposed payment reduction and instead ''conduct targeted claims review and deny payment for claims where the case-mix weight is not supported by the plan of care.'' In addition, some commenters recommended that CMS use existing medical review to identify and target specific agencies with abusive coding practices rather than imposing an across the board payment reduction, and one commenter stated that review by Medicare Administrative Contractors and edits can be used to determine if agencies are upcoding; the commenter believes that such a method would encourage accurate coding.

Response: We have taken various measures to reduce payment vulnerabilities and the federal government has launched actions to directly identify fraudulent and abusive activities. Commenters should be aware of tip lines available that can help

support investigative efforts of the federal government. The Office of the Inspector General, HHS Web site at *http://oig.hhs.gov/fraud/report-fraud/index.asp,* provides information about how to report fraud. Another Web site, *http://www.stopmedicarefraud.gov/index.html,* is oriented to Medicare patients and their families and provides information about recognizing fraud.

In addition, while we appreciate the commenters' suggestion about the claims review, we note that because our resources are not sufficient to conduct claims review on a scale that would be required to counteract the broad-based uptrend in case-mix weights, we cannot perform the review as suggested.

Furthermore, we note that our statistical methods using available administrative data are feasible and sufficiently reliable to utilize for the purpose of case-mix reductions.

Comment: A commenter requested that CMS adopt the approach outlined in the Home Health Care Access Protection Act of 2012 (H.R. 6059, 112th Cong.), which is sponsored by Rep. James McGovern and Rep. Walter Jones, and involves working with the home health industry to develop criteria and evaluating a medical records sample to determine reductions, rather than relying on hypothetical extrapolations.

Response: We already have commissioned a review of the case-mix change methodology, as we described in the CY 2012 proposed and final rule. A research team of highly qualified personnel evaluated our case-mix change methodology and found that, overall, our models to assess real and nominal case-mix growth are robust. We have not commissioned work analyzing case-mix change based on information from a medical records sample. We note that a medical records sample could be used to determine payment reductions; however, there are many difficulties and limitations to this analysis. First, to produce reliable results, we would need to collect a large sample, which would require significant financial resources that may not be available. We would need a sizable sample of records from both the IPS period and from a follow-up year (for example, 2009). In addition, based on our past experience in retrieving old records, it is difficult to find enough records to constitute a valid broad-based sample. Further, it is possible that using information from a medical records sample might not return the findings that the proponents suggest, because nominal case-mix increases partly result from reporting practices that have changed throughout time from a state of underreporting to a state of more complete reporting. Therefore, one would expect that the source records would likely reflect underreporting in the early years, just as the OASIS reflected underreporting in the early years.

Comment: A commenter stated that the CMS case-mix change methodology does not recognize the industry's increasing ability to care for more serious medical conditions in the home (caused by technology improvements, etc.) and ignores changes in patient severity. We received a number of comments stating that home health patients are now more complex with more co-morbidities and chronic conditions than in previous years and that patients that would have previously been referred to health care facilities, such as skilled nursing facilities, are now being cared for at home. Moreover, the commenters stated that other healthcare settings have developed stricter admission requirements, thereby increasing the number of home health patients with high severity levels. A commenter stated that Transitional Care Units (TCUs) and Skilled Nursing Facilities (SNFs) are refusing to accept complex patients from the hospital and implied that those patients were being diverted to home health care.

Response: To assess whether patients are more complex with more co-morbidities and chronic conditions than previous years, we examined the change in HCC variables over time, examining the average values for 2005 and 2010, the most recent complete data available. We note that our analysis did not find evidence that home health patients have gotten sicker over time as measured by the number of HCC indicators present. The mean number of HCC conditions present was the same in 2005 as in 2010. In addition, our analyses showed that while the prevalence of some HCCs has increased since 2005, the prevalence of others has decreased. Based on the relationship of individual HCC variables to case-mix level, the changes in the HCC indicators that have occurred since 2005 actually lead to a prediction of slightly lower expected case-mix. Furthermore, data we presented in the CY 2011 HH PPS final rule (75 FR 70379) indicate that hospital lengths of stay have been declining slightly and lengths of stay in residential post-acute settings before home health admission have increased between 2001 and 2008. We note that the proportion of initial non-LUPA home health episodes preceded by acute care within the previous 60 days has declined between 2001 and 2008, from 70.0 percent to 62.7 percent. This indicates more patients are being admitted to HHAs from non-institutional settings, such as from the community. Also, we note that acute care stays, which normally precede stays in institutional post-acute care settings, are decreasing in the stay histories of home health patients. Therefore, we question whether there is any evidence showing an increase in home health patient severity as a result of more patients coming to home health as a result of diversion from other post-acute care settings.

Comment: Commenters stated that CMS should suspend or eliminate case-mix payment reductions because the data used to determine the reductions do not recognize real increases in severity due to earlier and sicker hospital discharges.

Response: Although we recognize that average lengths of stay in acute care settings are in decline, our analysis shows that agencies are, in fact, caring for proportionately fewer, not more, post-acute patients. Since 2001, the average length of stay (LOS) in acute care preceding home health has declined by about one day, from 7 days to 6 days. Between 2008 and 2009, the average length of stay in acute care leading directly to home health admission declined from 6.07 days to 5.85 days. However, agencies are caring for fewer highly acute patients in their caseloads. The proportion of non-LUPA episodes in which the patient went from acute care directly to home health within 14 days of acute hospital discharge declined substantially between 2001 and 2008, from 32 percent to 23 percent. Also, the median acute hospital LOS for these non-LUPA episodes with a 14-day look back period remained unchanged at 5 days between 2002 and 2008 (see 75 FR 70379). In 2009, the median LOS declined to an estimated four days (see Table 2). The distribution of lengths of stay has been fairly stable, with declines since 2006 limited to the upper half of lengths of stay.

We believe the declining proportion of home health cases with a recent acute discharge is due in part to more patients incurring re-certifications after admission to home health care, and also due to more patients entering care from the community. The shortening lengths of stay at the right tail (high percentiles) of the distribution may reflect changing utilization of long-term-care hospitals during recent years. The conclusion we draw from these data is that while patients on average have shorter hospital stays, agencies are also facing a smaller proportion of home health episodes in which the patient has been acutely ill in the very recent past. Also, the detailed data on the distribution of stay lengths suggest that for the most

part lengths of stay for such patients remained fairly stable through 2009.

TABLE 2: Percentiles of Acute Hospital Length of Stay (Days) (2006-2009)

Year	5th	10th	20th	30th	40th	50th	60th	70th	80th	90th	99th
2006	1	2	3	3	4	5	6	7	9	12	28
2007	1	2	3	3	4	5	6	7	9	12	28
2008	1	2	3	3	4	5	5	7	8	12	27
2009	1	2	3	3	4	4	5	6	8	11	26

Note: Based on a 10 percent random beneficiary sample of FFS home health users; excludes LUPA episodes and includes only episodes where acute hospital discharge occurred within 14 days of the from-date of the 60-day episode claim and the patient's first destination post-discharge under Part A was home health care. Updates to the sample file are the likely reason for a few differences in percentile values from previously published data.

Furthermore, we think that acuity of patients has been increasingly mitigated by lengthening post-acute stays for the substantial number of home health patients who use residential post-acute care prior to an episode. Our data show that patients who enter residential post-acute care before home health admission have experienced increasing lengths of stay in post-acute care since 2001. Using a 10 percent random beneficiary sample, we computed the total days of stay (including both acute and post-acute care days) for home health episodes with common patterns of pre-admission utilization during the 60 days preceding the beginning of the episode. We included patients whose last stay was an acute care stay, or whose next-to-last stay was an acute care stay with a follow-on residential post-acute care stay, or whose third from last stay was an acute care stay followed by two post-acute care stays. These common patterns accounted for 55 percent of the initial episodes in 2001 and 42 percent in 2008. We found that total days of stay during the 60 days leading up to the episode averaged 12.6 days in 2001, and rose to 12.8 days in 2008. This small change in total days of stay during a period when acute care LOS was declining was due to increasing lengths of stay in residential post-acute care for these patients. For example, within the 30 days before admission, an average LOS in the post-acute care setting for episodes preceded by an acute care stay that was the next-to-last stay, and where the post-acute care stay was the very last stay before the claim from-date, increased from 12.7 to 14.3 days. Our interpretation of these statistics is that patient acuity has been increasingly mitigated by longer post-acute stays for the substantial number of home health patients that use residential post-acute care prior to the start of a home health episode. Patient acuity was also mitigated by growing numbers of home health re-certifications.

Comment: A commenter stated that the model used to assess real case-mix growth ignores the fact that more individuals are becoming eligible for Medicare services and there is an increasing number of Medicare beneficiaries who are over 85 years of age and need additional services.

Response: We note that increasing eligibility does not in itself imply more severity. Rather, our statistical analysis shows that there are more patients with about the same severity of illness level. With regards to the comment about the proportion of older patients, we note that we take into account the proportion of home health patients over the age of 85 in our model to estimate real case-mix growth. The results of the model show that while the proportion of patients over age 85 has increased somewhat, this change is only associated with small changes in real case-mix.

Comment: A commenter stated that relevant data shows that home health care patients have increased functional limitations and more complex clinical conditions than in past years.

Response: As stated in the CY 2012 proposed rule, a detailed analysis of Medicare Expenditure Panel Survey (MEPS) data (which is independent of our real case-mix model) was performed to examine the severity of the Medicare home health population. The trends in health status from 2000 to 2008 were analyzed.

The analysis showed a slight increase in the overall health status of the Medicare home health population, and in particular, the percent of home health Medicare beneficiaries experiencing ''extreme'' or ''quite a bit'' of work-limiting pain decreased substantially, from 56.6 percent in 2000 to 45.4 percent in 2008 (p=0.039). While we recognize that there are some limitations to this analysis, we concluded that the results of this analysis provide no evidence of an increase in patient severity from 2000 to 2008.

In addition, we would like to note that during the CY 2012 rulemaking cycle, we incorporated HCC data, which is used by CMS to risk-adjust payments to managed care organizations in the Medicare program, in our model to assess real case-mix growth. Our findings of real and nominal case-mix growth, even when incorporating HCC data, were consistent with past results. Most of the case-mix change was identified as nominal case-mix change.

We will continue to solicit suggestions for other data that can be

incorporated into our analysis of real and nominal case-mix growth.

Comment: A commenter stated the models used to determine real case-mix change do not consider increased therapy needs in the home health population.

Response: The models were intended to analyze real changes in case-mix over time and do not distinguish whether these changes are due to increases in therapy use or other factors. We do not believe that it would be appropriate to include utilization-related variables, such as the number of therapy visits, as predictors in the model, as such variables are provider-determined. In addition, the goal of these analyses was not to develop refinements to the payment system but rather to examine changes in measures of patient acuity that are not affected by any changes in provider coding practices. For example, the models do incorporate information about change in the types of patients more likely to use therapy, such as post-acute joint replacement patients. CMS has access to the claims histories and other administrative data for patients in our samples, and we welcome suggestions about how to better use these resources in finding alternative variables more indicative of the need for therapy, particularly if the suggestions involve the use of data and variables that are not HHA-determined.

Comment: Some commenters suggested that CMS recognize changes in patient severity, improved patient assessment, and coding and reimbursement changes in its case-mix methodology and work with NAHC to uncover the reasons for case-mix weight changes and to develop a valid methodology for payment reform. A commenter urged CMS to continue to evaluate and refine the case-mix methodology so that it targets drivers of case-mix change and more effectively captures real case-mix change. Another commenter stated that CMS should consult with stakeholders to agree upon factors that should be considered when calculating real and nominal case-mix growth.

Response: Through the public comment process, we have obtained industry views as to the reasons for coding changes. As we have pointed out in the past, reasons offered, such as improved coding, are not a sufficient basis for raising payment rates, particularly if data does not indicate a significant increase in the severity of home health patients. To the extent case-mix change is due to better methods of assessing patients in the home health setting, this does not justify making reimbursements as though the patients really were different in their case-mix levels of severity. Over the last several years, we have continued to evaluate our data and methods, and in the CY 2012 proposed and final rule, we described that we procured an independent review of our methodology to assess real and nominal case-mix growth performed by a team at Harvard University led by Dr. David Grabowski. The Harvard team was asked to review the appropriateness and strength of evidence from the case-mix change methodology we used. After their examination, they concluded that the methodology was robust and valid. We plan to continue to evaluate the case-mix methodology and potentially refine the methodology as needed. We will continue to solicit suggestions on possible ways to improve our models.

Comment: Commenters stated that providers have had to absorb several rounds of payment reductions due to upcoding, which have contributed to lower growth in home care spending. They stated that the growth rate in Medicare home care spending has dramatically declined to just 1.0 percent from 2010 to 2011.

Response: We note that the purpose of the payment reduction is to adjust payments to better reflect real changes in patient severity. In addition, slower Medicare home care spending growth may be due to a number of factors. We note that we have conducted analyses looking at the number of paid claims, both nationally and by state, for 2009 through 2011. Our analyses show that the volume of paid claims is consistent with previous years. Although paid claims generally go up very slightly every year and they did not in 2010, this could be attributed to many factors, including CMS's fraud and abuse efforts, or simply a more general trend in Medicare claims volume.

Comment: One commenter estimated that over 40 percent of existing HHAs currently operate with negative financial margins on Medicare revenues and that when all patient costs and revenues are considered, overall margins for all freestanding HHAs are estimated to be 3 percent in 2012. Another commenter stated that in the states where they operate, more than half or nearly half of all home health providers are reimbursed less than cost by Medicare. Specifically, the commenter stated that 59 percent of HHAs in Missouri, 45.9 percent of HHAs in Illinois, 59.0 percent of HHAs in Oklahoma, and 67.1 percent of HHAs in Wisconsin are operating with margins less than zero. The commenter urged CMS to eliminate the proposed 1.32 percent reduction so that payments more closely reflect the ''economic realities'' of HHAs.

Response: Regarding the commenters' concerns about the effects of the proposed reductions on providers' viability and the resultant access risks, we note that in their March 2012 Report to the Congress, MedPAC projected Medicare margins for home health agencies in 2012 to average 13.7 percent. While it is unclear whether the projection of average Medicare margins of 13.7 percent in 2012 factors in potential changes in the therapy level distribution due to the CY 2012 recalibration, and therefore actual margins could be slightly different, we note that our analysis of payments and costs also projects average margins to be adequate. Furthermore, when examining the impact of the 1.32 percent payment reduction, providers need to take into account all of the other policies in the CY 2013 rule, such as changes to the fixed dollar loss (FDL) ratio as well as the wage index and payment update. When examining all of the CY 2013 policies finalized in this final rule, our data indicates that the impact is minimal, with an average effect on payments of −0.01 percent. In addition, when taking into account all of the CY 2013 policies, Illinois, Wisconsin, and Missouri are expected to have a net increase in payments in CY 2013 (see section IV. Regulatory Impact Analysis). Furthermore, based on the results of our analysis on estimated margins by state, there is no indication that the four states mentioned by the commenter will be more adversely affected by the CY 2013 policies compared to other states.

Comment: A commenter stated that while the number of HHAs may continue to grow, the growth is limited to certain geographic areas and that the across the board payment reductions are ''taking their toll'' on HHAs with below average margins. Another commenter stated ''Any efficiency available to control the cost of an episode of care has been implemented, and rate cuts are now having a direct, linear impact of providers.''

Response: We note that our analysis of margins and MedPAC's reported margins for 2010 indicate that payments should be adequate. In addition, we reiterate that the purpose of the payment reduction is to align payment with real, observed changes in patient severity. Moreover, while we considered a 2.18 percent reduction to the national standardized 60-day episode rates based on our analysis using 2010 data, we are finalizing a 1.32 percent payment reduction for this year.

Comment: A commenter stated that the case-mix model used to determine

real case-mix growth does not account for real case-mix changes in patient severity experienced by hospital-based home health agencies and that the proposed payment reduction would adversely impact hospital-based home health agencies. Commenters stated that the data used to calculate the case-mix reduction is skewed to free-standing facilities and that free-standing HHAs are selective while hospital-based HHAs take on all types of patients discharged from the hospital. The commenters did not think the reduction was appropriate for hospital-based home health care. Another commenter stated that hospital-based HHAs average Medicare margin was -6.29 percent in 2010 and that it can be assumed that overall margins of this HHA sector is well below zero percent given lower-than-cost Medicaid and Medicare Advantage payment rates.

Response: In the CY 2012 proposed and final rule, we described the results of the independent review of our models to assess case-mix growth performed by a team at Harvard University led by Dr. David Grabowski. We described that 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. Two of the extensions that we examined focused on free standing and facility-based HHAs. The extensions showed a large and not dissimilar rate of nominal case-mix growth from 2000 to 2008 for the two groups, 17.86 percent nominal case-mix increase for free-standing HHAs and 14.17 percent nominal case-mix increase for facility-based increase. Given the results of our analysis, which showed significant nominal case-mix growth for freestanding versus hospital based HHAs, we believe that the model is not skewed to a particular provider type and that an across the board reduction is appropriate given the widespread nominal case-mix growth. We note that our analysis on Medicare Cost Report data for hospital-based HHAs does indicate that Medicare margins are lower than those of freestanding HHAs.

Comment: Commenters criticized the model's reliance on hospital data, stating that over half of all Medicare home health patients are admitted to care from a setting other than a hospital and many of the patients receive home health care far extended past an initial episode. Commenters implied that the All Patient Refined Diagnosis Related Groups (APR–DRG) variables are less relevant for multiple episode patients.

Response: We disagree that the use of the hospital information in the case-mix change analysis is so limited. Also, with the addition of HCC data, we have enhanced the robustness of the variable set used for the analysis to include physician diagnoses and diagnoses of other clinicians, as well as Medicaid eligibility. Regardless of whether the patient came directly from a non-hospital-setting (for example, home or an institutional post-acute stay), information from a hospital stay preceding home health is typically relevant to the type of patient being seen by the HHA.

Comment: A commenter stated that case-mix reductions do not take into account the cost of new regulatory burdens, such as documentation for face-to-face encounters and HHCAHPS.

Response: We note that the 1.32 percent payment reduction is to account for nominal case-mix increases (increases in case-mix that are not related to real changes in patient acuity). Case-mix reductions are not intended take into account the costs of regulatory burdens. The models used to assess real case-mix growth take into account factors that would affect patient severity.

Comment: A commenter stated that nominal case-mix growth cannot be assumed using CMS's methodology because of the change from ICD–9 to ICD–10.

Response: Our analysis of case-mix used data from 2000 to 2010 to determine the amount of real and nominal case-mix growth and did not take into account a change from ICD–9 to ICD–10. The change is currently not relevant to our analysis of case-mix growth. After we transition from ICD–9 to ICD–10, we may examine the effects of the change on case-mix growth as data become available and propose payment adjustments accordingly.

Comment: One commenter said that the payment reductions to account for nominal case-mix growth are arbitrary and appear to reduce payments without data to show that they are necessary.

Response: We disagree. The prediction model for real case-mix is an empirical model, the findings of which are based entirely on empirical evidence. The real case-mix prediction model and its application account for changes in the HH patient population by quantifying the relationships between patient demographics, clinical characteristics, and case-mix. The relationships in conjunction with updated measures of patient characteristics are used to quantify real case-mix change. The characteristics in the model include proxy measures for severity, including a variety of measures, namely, demographic variables, hospital expenditures, expenditures on other Part A services, Part A utilization measures, living situation, type of hospital stay, severity of illness during the stay, and risk of mortality during the stay. Last year, additional diagnosis data, based on physician and hospital diagnoses in the patient's claims history, were added in the form of HCC indicators. Measurable changes in patient severity and patient need, factors mentioned by commenters, are an appropriate basis for changes in payment. Our model of real case-mix change has attempted to capture such increases.

We recognize that models are potentially limited in their ability to pick up more subtle changes in a patient population such as those alluded to by various commenters. Yet in previous regulations we presented additional types of data suggestive of only minor changes in the population admitted to home health, and very large changes in case-mix over a short period. We included among these pieces of evidence information about the declining proportion of home health episodes associated with a recent acute stay for hip fracture, congestive heart failure, stroke, and hip replacement, which are four situations often associated with high severity and high resource intensity (72 FR 49762, 49833 (August 2007)). We presented information showing that resource use did not increase along with case-mix increases (72 FR 49833). We also analyzed changes in OASIS item guidance that clarified definitions and could have led to progress in coding practice (72 FR 25356, 25359 (May 2007)). We found some small and scattered changes indicative of worsening severity but these changes did not commensurate with the increase in case-mix weights (72 FR 25359). In our discussion, we cited specific instances where agencies' changing understanding of coding could have contributed to the adverse changes. However, as previously stated, Medicare payments should be based on patient level of severity, and not on coding practices.

In the CY 2011 HH PPS proposed rule, we identified a very large, sudden 1-year change (+0.0533) in the average case-mix weight between 2007 and 2008. This increase is partly attributable to the reporting of secondary diagnosis codes (see 75 FR 43242 (July 23, 2010)). The use of secondary diagnosis codes in the case-mix algorithm was introduced

in 2008 as part of the new case-mix system.

In summary, we believe the payment reductions to account for nominal case-mix growth are not arbitrary and data used in our model as well as other data indicate only small changes in patient severity while we have observed large changes in the average case-mix weight over time. Therefore, in order to better align payment with real changes in patient severity, we are finalizing a 1.32 percent payment reduction for CY 2013.

Comment: One commenter stated that the actual program spending on home health is generally less than the Congressional Budget Office estimates between 1996 to 2009. Therefore they questioned CMS's authority to implement payment reductions for nominal case-mix growth. They stated that in home health, Medicare expenditures have been equal to or lower than projections and estimates by CBO since the beginning of the HH PPS and therefore, there is no increase in aggregate expenditures that warrants application of the statutory authority under section 1895(b)(3)(B)(iv) of the Act.

Response: Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions if there are changes in aggregate payments that are a result of nominal case-mix growth. Our data show changes in actual aggregate payments due to nominal case-mix growth, and therefore in the CY 2013 HH PPS proposed rule, we proposed to move forward with a 1.32 percent reduction to the HH PPS rates.

Comment: A commenter stated that across the board reduction can cause or exacerbate access issues for high-cost patients. Another commenter stated that they are seeing access problems for higher-cost patients. The commenter suggested that CMS evaluate the payment model to determine whether changes are needed to address the unintended impact of the across the board rates on providers and evaluate the payment model based on its ability to maintain access to care for all eligible Medicare beneficiaries. Commenters urged CMS to make modifications to the payment system so that there are not financial disincentives to accepting a disproportionate number of high cost patients.

Response: We appreciate the commenter's concerns. 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''). Pending results of the study, CMS may make recommendations for revisions to the HH PPS and recommendations for legislation and/or administrative action which may address any access issues identified in the study. In addition, we will continue to monitor for unintended consequences of the payment reductions and we will seek information from other government agencies on access. Finally, we will use Open Door Forums and other venues to solicit information from agencies on any actual access issues they witness.

Comment: A commenter stated that CMS should use information from the home health study under section 3131(d) of the Affordable Care Act to determine a fair payment rate rather than imposing across the board payment reductions.

Response: The home health study under section 3131(d) of the Affordable Care Act allows CMS to not only look at access for vulnerable populations, but also look at other issues with the payment system and payment vulnerabilities. In this study, we plan to examine ways to better align payment with patient needs. The Report to Congress describing the findings of our study is projected to be available in 2014. In the meantime, while examining ways to better improve the case-mix system, we believe that it is appropriate to adjust payment rates to reflect real, observed changes in patient severity.

Comment: One commenter stated that they were concerned with the 1.32 percent payment reduction since it is combined with the Affordable Care Act mandated 1 percent reduction to the market basket update. The commenter urged CMS to recognize home health as a critical part of the health care continuum and that it requires adequate reimbursement to succeed in a reformed health care delivery system. The commenter stated that home health agencies should be reimbursed adequately for their services and that home health services are less expensive than acute care alternatives. Another commenter stated that overall Medicare spending has increased much more than Medicare payments to home health agencies and that the payment reductions to home health care spending ''represents negative health policy at a time when we should be encouraging the provision of health care outside of facilities.'' The commenter continued to say that hospital inpatient and long-term acute care hospitals will see increases in their payments for CY 2013. The commenter stated that CMS should not be cutting the most cost effective portions of the health care system to provide greater reimbursement to the most expensive ones. The commenters asked CMS to reconsider the 1.32 percent coding adjustment and other payment reduction changes in the 2013 HH PPS rule.

Response: We thank the commenters for their comments. However, we note that the 1 percent reduction to the market basket update is a mandated payment reduction, not intended to be offset by other policies, such as the 1.32 percent payment reduction. In addition, the Regulatory Impact section of our rule (see section VII.) shows that when combined with the market basket update and the wage index update, this rule will have a minimal impact on payment in comparison with previous years. In addition, while we updated our analysis to include 2010 data, which would have resulted in a 2.18 percent payment reduction, we are finalizing a 1.32 percent reduction for this final rule. We would also like to remind commenters that the goal of the payment reduction is to better align payment with real changes in patient severity. That is, the payment reduction is to ensure appropriate payment given the real changes in the Medicare home health population we observe. We would also like to point out that the 1.32 percent payment reduction is not related to the increase in payments for hospital inpatient and long term acute care hospitals; that is, the payment reduction does not free up money to pay for other settings. The goal of the payment reduction is to pay appropriately for the home health services provided to Medicare home health beneficiaries.

Comment: Several commenters stated that they support and appreciate CMS's proposal to withhold any further increase in the payment reduction to account for nominal case-mix growth. Commenters stated that the 1.32 percent payment reduction, rather than the full 2.18 percent reduction is a welcome action from CMS as providers have experienced significantly increased costs with the face-to-face encounter and therapy assessment requirements. Another commenter stated that the restraint in the payment reduction to account for nominal case-mix growth is warranted because the 2010 data does not yet fully reflect changes in CMS

policy that were intended to reduce some of the nominal increases in case-mix weights. Commenters stated that they would like CMS to limit the 2013 adjustment for nominal case-mix growth to 1.32 percent as proposed in the CY 2013 proposed rule.

Response: We appreciate the commenters' support of our proposal. We would like to clarify that the reason the 1.32 percent payment reduction, rather than the full 2.18 percent reduction, was proposed was not because of any potential additional costs associated with the face-to-face encounter and therapy assessment rules. We believe the 2.18 percent payment reduction would allow CMS to fully account for the nominal case-mix growth from 2000 to 2010 and we may consider accounting for more nominal case-mix growth in future rulemaking. However, given certain factors, such as the recent recalibration in CY 2012 and potential effect on the average case-mix, for this final rule, we are finalizing a 1.32 percent reduction to account for nominal case-mix growth, as described in the CY 2012 final rule.

Comment: One commenter stated that unwarranted overpayments attributable to changes in coding practices should be recovered and that payment increases unrelated to patient severity also occur in other payment systems. The commenter stated that the proposed adjustment would not account for all of the coding increase CMS has identified and that the proposed adjustment would result in overpayments to home health agencies, increasing home health expenditures for the federal government and beneficiaries. The commenter stated that aggregate Medicare margins in 2012 are projected to exceed 13 percent and that with the full reduction of 2.18 percent, most HHAs would be paid well in excess of costs. The commenter stated that implementing a small reduction in 2013 will require that a larger reduction occur in future years and therefore, CMS should reduce payments by 2.18 percent in 2013.

Response: We thank the commenter for the comments. We agree that the 2.18 percent reduction would allow CMS to fully account for the nominal case-mix growth through 2010. However, due to certain factors such as the recalibration in CY 2012, the average case-mix weights may have lowered and therefore, for this final rule, we are finalizing a more conservative payment reduction of 1.32 percent. It is unclear whether the projection of average Medicare margins of 13 percent in 2012 factors in potential changes in the therapy level distribution due to the CY 2012 recalibration. We will continue to assess nominal case-mix growth and propose reductions in future rulemaking as necessary.

Comment: One commenter stated that the yearly recalculation of revision of the payment reduction to account for nominal case-mix undermines the stability of the payment system and CMS's proposals have made it hard for HHAs to predict the payment amounts.

Response: We disagree there has been instability. Since 2008, agencies have been informed that payments would be reduced over time to offset unwarranted reimbursement growth due to nominal case-mix growth and every year since 2008, we have applied a payment reduction to account for nominal case-mix growth. Also, every year since CY 2011 rulemaking, we have updated our analysis of real and nominal case-mix growth as data have become available and in CY 2011 and CY 2012 rulemaking, our updated analysis resulted in further payment reductions to the national standardized 60-day episode rates. We note that for CY 2013, we are finalizing a 1.32 percent reduction, as described in the CY 2012 final rule. In addition, we reiterate that the purpose of the payment reduction is to adjust payments to better reflect real changes in patient severity and our goal is to pay appropriately for the home health services provided to Medicare home health beneficiaries.

Comment: Commenters were concerned with the impact of the 1.32 percent payment reduction on quality of care.

Response: Commenters did not provide specific information about why they believe payment reductions might impact quality of care. Our simulation of margins under the payment policies in this rule suggests that margins will remain adequate, and thereby not have an adverse effect on quality of care. We also believe that policymaking in the quality improvement area should help to ensure quality advances. OASIS–C outcome reports and HHCAHPS data are two important recent developments that we anticipate will support high-quality services. Over time, value-based purchasing policies will be developed, further enhancing quality-related incentives. We encourage agencies to work to their full professional potential to deliver a high standard of care to their patients.

Comment: A commenter stated that payment reductions will decrease the agencies' ability to educate, focus on quality care, implement electronic systems of documentation, and focus on savings to the Medicare program such as decreasing hospitalizations. They stated that payment reductions would mean fewer resources to develop quality and compliance programs.

Response: A reduction in margins as a result of our payment changes may have an effect on the availability of resources for various types of investments. However, our analysis indicates that payments to HHAs will still be more than adequate under our payment changes and would still allow for investments. We do not have sufficient data to evaluate the effect on technology-specific investments from the unusually large margins that have been in existence under the HH PPS, but we welcome information about whether the numerous agencies that operated with high margins under the HH PPS made investments during those years, and the nature of those investments. Other areas, such as education, quality improvement, and decreasing hospitalizations, are the focus of investment in human capital that agencies should be currently undertaking in view of program initiatives underway or being tested (HHCAHPS, HH P4P demo). We reiterate that our analysis of payments indicates that payments are adequate enough to allow for different types of quality-strengthening investments, whose costliness would depend on the agency's individual situation, including how efficiently the agency operates in general. We would also like to note that the pay for performance (P4P) demonstration did not find strong evidence that changes participating agencies made along the lines of better care coordination to improve quality and reduce hospitalizations were necessarily expensive (*http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/HHP4P_Demo_Eval_2008_Vol3.pdf*).

In the CY 2012 final rule, we finalized a 3.79 percent payment reduction to the CY 2012 national standard 60-day episode rates and a 1.32 percent payment reduction to the CY 2013 national standardized 60-day episode rates to account for nominal case-mix growth we identified from 2000 to 2009. In the CY 2013 proposed rule, we updated our analysis using data from 2000 to 2010, estimating that the percentage reduction to account for nominal case-mix change would be 2.18 percent. However, we proposed a 1.32 percent payment reduction as described in the CY 2012 rule. For this final rule, we are finalizing a 1.32 percent payment reduction for CY 2013 to the national standardized 60-day episode rates. This reduction enables us to account for nominal case-mix growth which we have identified through CY 2009 and to

collect additional data on case-mix change, such as data on the effects of the CY 2012 recalibration of the HH PPS case-mix weights.

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 do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. To mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we adopted an outlier policy that included a 10 percent agency level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total HH 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 we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act. As revised, ''Adjustment for outliers,'' states that ''The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to home health services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to 5 percent of the total payments estimated to be made based on the prospective payment system under this subsection for the period.'' In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act, and revising it to state that the Secretary, ''subject to [a 10 percent program-specific outlier cap], may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph 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 do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

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. 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. We did not propose a change to the loss-sharing ratio in the CY 2013 HH PPS proposed rule issued in the July 13, 2012 **Federal Register** (77 FR 41548).

For the proposed rule, based on simulations using CY 2010 claims data, we estimated that outlier payments in 2012 will comprise approximately 2.12 percent of total HH PPS payments. However, we did not propose a change to the FDL ratio in the CY 2013 HH PPS proposed rule. This was, in part, because we were not able to verify these projections in our paid claims files since

implementing 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 were currently underway, and thus the CY 2010 data file used in our analysis for the CY 2013 HH PPS proposed rule reflected outlier payments with these claims processing errors. In the CY 2013 HHS PPS proposed rule we stated that we would update our estimate of the FDL ratio for the final rule using the best analysis the most current and complete year of HH PPS data.

5. Outlier Relationship to the HH Payment Study

As we discussed in the CY 2013 HH PPS proposed rule, section 3131(d) of the Affordable Care Act requires us 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 projected to be available in 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.

The following is a summary of the comments we received regarding the outlier policy in the CY 2013 HH PPS proposed rule.

Comment: A commenter stated that CMS's policy of reducing the outlier pool from 5 percent to 2.5 percent and capping, per provider, outlier revenues at 10 percent has negatively impacted HH providers. The commenter stated that in certain areas, HHAs provide services to predominantly high-cost beneficiaries with chronic conditions like HIV/AIDS or with mental health needs and developmental disabilities. HHAs that provide services to a high-cost population have reported being negatively impacted by the 10 percent outlier cap. The commenter requested that CMS exempt special-needs HHAs that serve high-cost patients with multiple clinical issues from the 10 percent outlier cap. The commenter also believes that CMS should raise the outlier cap so that all HHAs that serve high-cost beneficiaries can continue to do so without losing outlier funding.

Response: We do not have the statutory authority to change the 2.5 percent outlier pool, the 5 percent reduction to the HH PPS payment rates to fund the outlier pool, or the 10 percent outlier cap. Section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5)(A) of the Act to require that the total amount of the additional payments or payment adjustments made with respect to outliers in 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 in that year. Section 3131(b)(2)(C) of the Affordable Care Act added section 1895(b)(5)(B) of the Act so that CMS is required to apply a 10 percent agency-level outlier cap in each year. The statute does not provide for exemptions to the 10 percent cap based on resource use or otherwise.

Comment: A commenter requested that CMS develop a remedy to the limitations in the current outlier policy in actually addressing high cost cases.

Response: We reiterate that we intend to analyze alternatives to our current outlier policy as part of the home health study mandated by section 3131 of the Affordable Care Act. The study calls for us to investigate improvements to the HH PPS to account for patients with varying severity of illness.

Comment: Several commenters supported CMS's proposal to maintain the current FDL ratio in determining outlier payments, while several others were disappointed that the CY 2013 HH PPS proposed rule did not include any adjustments to the FDL ratio, especially given the analysis that projects that total outlier payments in 2011 and 2012 have been significantly below the 2.5 percent target. Commenters stated that CMS should recalculate outlier payment levels for 2011 and 2012 now that the claims processing errors for outliers have been corrected, and consider revising the CY 2013 FDL ratio in the event that total outlier spending is less than 2.5 percent. One commenter believed that recent outlier claims processing flaws, when resolved, are likely to affect the total outlier spending in 2011 such that outlier payments will comprise more than the estimated 2.12 percent of total HH PPS payments in outlier payments.

Response: Since the publication of the CY 2013 HH PPS proposed rule, we were able to correct the two claims processing errors that resulted in inaccuracies in outlier payment amounts in our paid claims files for CY 2010 and 2011. Analysis of corrected claims data and updated simulations using CY 2010 claims data show that outlier payments in 2013 are estimated to comprise approximately 2.18 percent of total HH PPS payments. As a result, in order to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments, the FDL ratio would need to be revised to 0.45 for CY 2013.

Analysis of corrected claims data and updated simulations using CY 2010 claims data show that outlier payments in 2013 are estimated to comprise approximately 2.18 percent of total HH PPS payments. As a result, we are finalizing an FDL ratio of 0.45 percent in order to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments. We believe that our new outlier policy for CY 2013 of using an FDL ratio of 0.45 and a loss-sharing ratio of 0.80 strikes an effective balance of compensating for high cost episodes while allowing more episodes to qualify for outlier payments.

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 through 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 described 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. In the CY 2013 HH PPS proposed rule (77 FR 41548), we proposed 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 proposed 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 the 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 also proposed changes to the wage and benefit price proxies used in the HH market basket. We also proposed 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 proposed to revise the price proxies for the Insurance and Transportation cost categories. Finally, we proposed the use of four new price proxies for the four additional cost categories.

The major cost weights for the 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 referred 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 proposed 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 reported costs were less than zero), we then determined the proportion of total costs that each category represented. 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 proposed 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 proposed 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 2010-based index and those used for the current 2003-based index are summarized in Table 3. We have allocated the Contract Services weight to the Wages and Salaries Employee Benefits, A&G, and Other Expenses cost categories in the 2010-based index as we did in the 2003-based index.

TABLE 3: Comparison of 2003-Based and the 2010-Based Home Health Market Baskets Major Cost Categories and Weights

Cost Categories	2003-Based Home Health Market Basket	Final 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 2010-based cost categories and weights are listed in Table 4.

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TABLE 4: Cost Categories, Weights, and Price Proxies in the 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	Home Health Occupational Wage Index (2010)
Employee Benefits, including allocated contract services' labor	12.210	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.

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After we computed the CY 2010 cost category weights for the 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 professional liability insurance costs, the 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 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 proposed to revise and rebase the home health blended Wage and Salary index and the home health blended Benefits index. We proposed to use these blended indexes as price proxies for the Wages and Salaries and the Employee Benefits portions of the 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 proposed to apply six price proxies to six occupational subcategories within the Wages and Salaries component, that reflect the HHA occupational mix.

The 2003-based blended wage index was comprised of four occupational subcategories proxied by five wage proxies. For the 2010 blended wage index, we proposed to further disaggregate the service workers occupations into health and social assistance service and other service occupational groups. We also proposed to explicitly disaggregate professional and technical (P&T) workers into health-related P&T and non health-related P&T workers. We proposed 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. 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. Table 5 compares the 2010 occupational assignments of the six CMS designated subcategories to the 2003 occupational assignments of the four CMS designated subcategories.

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TABLE 5: 2010 Occupational Assignments compared to 2003 Occupational Assignments for CMS HH Wage Composite Index

2010 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	39-0000	Personal Care and Service

2010 Occupational Groupings		2003 Occupational Groupings	
	Related Occupations		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		
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 6. We determined the proportion of total wage costs that each subcategory represents. These proportions listed in Table 6 represent the major rebased and revised home health blended Wage and Salary index weights.

TABLE 6: Home Health Occupational Wages and Salaries Index (Wages and Salaries Component of the 2010 Based Home Health Market Basket)

Cost Category	2003 Weight	2010 Weight	Price Proxy	BLS Series ID
Health-Related Professional and Technical (P&T)	25.406	33.373	ECI for Wages & Salaries for Civilian Hospital Workers	CIU1026220000000I
Non Health-Related P&T	25.406	2.253	ECI for Wages & Salaries in Private Industry for Professional, Specialty & Technical Workers	CIU2025400000000I
Managerial/ Supervisory	9.007	8.260	ECI for Wages & Salaries in Private Industry for Executive, Administrative & Managerial Workers	CIU2020000110000I
Administrative / Clerical	7.596	7.720	ECI for Wages & Salaries in Private Industry for Administrative Support, Including Clerical Workers	CIU2020000220000I
Health and Social Assistance Services	--	35.772	ECI for Wages & Salaries for Civilian Healthcare and Social Assistance	CIU1026200000000I
Other Service Occupations	32.584	12.622	ECI for Wages & Salaries in Private Industry Service Occupations	CIU2020000300000I
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 2010-based home health wage and salary blend is shown in Table 7. The average annual increase in the two price proxies is similar, and in no year is the difference greater than 0.2 percentage point.

TABLE 7: Annual Growth in the 2010 HH Wage Blend and 2003 HH Wage Blend

	2010	2011	2012	2013
HH Wage Blend 2010	1.6	1.5	1.9	2.5
HH Wage Blend 2003	1.5	1.5	1.7	2.3

Source: IHS Global Insight, Inc, 3rd Quarter 2012 forecast with historical data through 2nd Quarter 2012.

- *Employee benefits:* For measuring employee benefits price growth in the 2010-based home health market basket, we proposed to apply applicable price proxies to the six occupational subcategories that are used for the wage blend listed in Table 8. The percentage change in the blended price of home health employee benefits is applied to this component, which is described in Table 8.

TABLE 8: Home Health Occupational Benefits Index (Employee Benefits Component of the 2010-Based Home Health Market Basket)

Cost Category	2003 Weight	2010 Weight	Price Proxy
Health-Related Professional and Technical (P&T)	25.253	33.506	ECI for Benefits for Civilian Hospital Workers
Non Health-Related P&T	25.253	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		35.887	ECI for Benefits for Civilian Healthcare and Social Assistance Workers
Other Service Occupations	33.024	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 proposed 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 2010-based home health benefit blend is shown in Table 9. 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 9: Annual Growth in 2010 HH Benefits Blend and 2003 HH Benefits Blend

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

Source: IHS Global Insight, Inc, 3rd Quarter 2012 forecast with historical data through 2nd Quarter 2012.

- *Administrative and Support:* We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. We currently do not have a PLI index specific to the HHA industry so we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to revise the price proxy to reflect price inflation of both private and public transportation costs. We proposed this change as further investigation of the MCR instructions request providers to include both private and public transportation costs.
- *Fixed capital:* We proposed 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 proposed 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 2010-based home health market basket is shown in Table 10.

TABLE 10: Comparison of the 2003-Based Home Health Market Basket and the 2010-Based Home Health Market Basket, Percent Change, 2010-2013

	Home Health Market Basket, 2003-Based	Home Health Market Basket, 2010-Based	Difference (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	1.8	2.0	0.2
CY 2013	2.1	2.3	0.2
Average Change: 2010-2013	1.9	2.0	0.1

Source: IHS Global Insight, Inc, 3rd Quarter 2012 forecast with historical data through 2nd Quarter 2012;

Table 10 shows that the forecasted rate of growth for CY 2013, beginning January 1, 2013, for the rebased and revised home health market basket is 2.3 percent, while the forecasted rate of growth for the current 2003-based home health market basket is 2.1 percent. The higher growth rate for the 2010-based HHA market basket for CY 2013 is primarily attributable to the wage blended price proxies. The revised wage 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 ECI for hospital workers is 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 revised and rebased home health market basket, the labor-related share is 78.535 percent. The labor-related share includes wages and salaries and employee benefits, as well as allocated contract labor costs. The non-labor-related share is 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 11 details the components of the labor-related share for the 2003-based and 2010-based home health market baskets.

TABLE 11: Labor-Related Share of Current and 2010-Based Home Health Market Baskets

Cost Category	2003-Based Market Basket Weight	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. CY 2013 Market Basket Update for HHAs

For CY 2013, we proposed to use an estimate of the 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.

In the proposed rule, based on IGI's second quarter 2012 forecast with history through the first quarter of 2012, the HHA market basket update for CY 2013 was projected to be 2.5 percent. Consistent with historical practice, we also proposed 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. Therefore, we are finalizing a CY 2013 market basket update of 2.3 percent for CY 2013, which is based on IGI's third quarter 2012 forecast with history through the 2nd quarter 2012.

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 final CY 2013 market basket update of 2.3 percent must be reduced by 1 percentage point. Thus, the CY 2013 home health payment update is 1.3 percent.

The following is a summary of the comments we received regarding the CY 2013 Rate Update proposal.

Comment: Several commenters supported the proposed effort to rebase and revise the market basket in order to update the cost shares from a 2003 base year to a 2010 base year. One commenter believed that future rebasings and revisions may be needed every 5 years or less due to the rapidly changing landscape of health care and home health services.

Response: We appreciate the commenters' support for the proposed rebasing and revising of the market basket to reflect 2010 cost data. We also acknowledge the public's concern regarding the changing landscape of costs. We will monitor the market basket's cost categories and their respective weights in order to ensure they remain contemporary and representative of the industry's cost structure.

Comment: One commenter expressed concerns about the quality of the cost report data that are submitted to CMS. The commenter noted that they are hopeful that the recent audits of the cost reports that CMS has initiated will improve the quality of the data. The commenter noted that although they have concerns about the quality of the cost report data they still support the proposed rebasing and revising of the market basket to 2010.

Response: In regards to the commenter's concern on the quality of the cost report data, when we calculate the market basket cost weights, we run various trimming scenarios to be sure the final market basket cost weights are not adversely impacted by outliers. We also run matched samples and compare trends and cost shares over time. Therefore, we believe our resulting market basket cost weights are representative of the national average of freestanding home health agencies.

Comment: One commenter questioned the accuracy with which the market basket accounts for transportation costs, currently, as well as under the proposed methodology. They note that transportation costs have become more unpredictable with the increasing and fluctuating cost of gasoline.

Response: We believe the Transportation cost weight within this market basket accurately captures the relative costs faced by home health providers as we obtain these costs directly from the Medicare cost reports. Additionally, this particular category's cost weight has been notably consistent, ranging from between 2.5 percent and 2.8 percent over the last several years.

For the price proxy used to estimate price changes for this category of costs, although we agree that there is volatility in the price of gasoline, we feel that the CPI–U for Transportation price index, developed and published by the Bureau of Labor Statistics appropriately reflects these costs. Within this particular CPI, motor fuel represents approximately 1/3rd of its cost weight (with new and used motor vehicles and motor vehicle insurance comprising most of the remaining share). This index also appropriately meets CMS's guidelines for price proxies (relevance, reliability, timeliness, and public availability).

Comment: Several commenters expressed concern that CMS only uses data from freestanding home health agencies to determine the market basket cost shares. One commenter also specifically noted the possible difference in the labor portion of the market basket and the impact on the payments based on the geographic differences. They noted that while there is concern about the attribution of costs to hospital-based providers, those shifts would appear in the indirect cost centers. They also noted that wages and salaries and benefits should be comparable across freestanding and hospital-based providers since they are direct costs and therefore the hospital-based data should be incorporated into the calculation of the labor-related share.

Response: Presently, all of CMS's market baskets, or input prices indexes, incorporate data from only freestanding providers. We monitor the costs and cost structures of both freestanding and hospital-based providers in the home health industry, as well as other industries. Despite controlling for the differing characteristics of both provider types, including their respective patient case mix, their geographic locations, and other relevant factors, we were not able to adequately explain the variation in costs between the two provider types. Consequently, we believe that it is appropriate to base the market basket's structure on free-standing providers only. We will continue to monitor and attempt to better understand these differences going forward.

Comment: One commenter believed that the market basket should be based on 2011 cost report data and that 2010 cost reports do not reflect the increases in costs to providers of the face-to-face and therapy reassessment requirements.

Response: The market baskets are always based on the most current and complete set of cost report data. At the time of this rebasing, the most current and complete set of data was for 2010. We will monitor the 2011 cost reports as they become available and, if the cost structure of the industry is materially different than it was in 2010, we would consider proposing a subsequent rebasing.

Comment: Several commenters support the resulting increase to the labor-related share which results from the rebasing of the market basket cost shares.

Response: We believe the cost shares that are determined based on this rebasing represent the current national average cost shares of the industry. Thus, we are finalizing those cost shares in this final rule.

Comment: Several commenters expressed concerns with the proposal to increase the labor-related share from 77.082 percent to 78.535 percent for CY 2013 and asked CMS to provide more clarity on the calculation methodology. One commenter notes that the resulting increase to the labor-related share will have a significant negative impact on providers, particularly those in rural areas.

Response: The home health market basket's labor-related share is based on the sum of the weights for Wages & Salaries and Benefits. The labor-related share is estimated based on actual data submitted on the home health Medicare cost report for both rural and urban freestanding home health facilities and is intended to reflect the national average. The proposed change in the labor-related share is primarily attributable to the update of the base year to reflect 2010 data. The 2010 data, the most recent and comprehensive data available at the time of the rebasing, show that labor-related costs have increased faster than aggregate non-labor-related costs since 2003. Although we will continue to analyze the home

health Medicare cost report data on a regular basis to ensure it accurately reflects the cost structures facing home health providers, we believe the proposed 78.535 percent labor-related share appropriately reflects the current national average.

Comment: One commenter believed the market basket should reflect cost changes in an episode of care rather than annual total costs for the home health agency. The commenter requested that CMS provide an explanation of how the market basket index and the changes in episode costs relate to one another. They noted that the average episode of care in 2010 could include a different mix of disciplines than an average episode of care in 2003.

Response: 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. Specifically the statute states: ''The standard prospective payment amount (or amounts) shall be adjusted for fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004) in a prospective manner specified by the Secretary by the home health applicable increase percentage (as defined in clause (ii)) applicable to the fiscal year or year involved.'' Given that the weighted changes in episode costs, including the changing mix of disciplines required to provide home health services, all flow into the Medicare cost report, they are thus reflected in the market basket's respective cost weights.

As a result of the comments, we are finalizing all of the proposed changes to the home health market basket. The base year will reflect the 2010 cost shares as proposed and all of the price proxies that were proposed will be implemented. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a CY 2013 market basket update of 2.3 percent for CY 2013, which is based on IGI's third quarter 2012 forecast with history through the 2nd quarter 2012. Additionally, we are finalizing the labor-related share that reflect the 2010 wage and benefit cost shares of the market basket, which is 78.535 percent.

Comment: A commenter expressed concern about the impact of the reduction to the market basket update.

Response: The reduction to the market basket update is legislated by section 1895(b)(3)(B) of the Act, as amended by section 3401(e) of the Affordable Care Act, which states that the Secretary shall reduce the market basket percentage by 1 percentage point for 2011, 2012, and 2013.

Comment: We received several comments regarding CMS's efforts in rebasing the HH payment rates as mandated by the Affordable Care Act. We also received comments pertaining to the automatic, across-the-board cuts, known as sequestration, that are included in the Budget Control Act of 2011.

Response: The comments are outside the scope of this rule. However, we will consider the comments concerning rebasing in our future rebasing efforts.

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 FR68575), we finalized that we will 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, constitutes 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 (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 (72 FR 49863), HHAs that become Medicare-certified on or after May 31 of any year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following calendar 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

In the CY 2013 HH PPS proposed rule (77 FR 41548), we proposed 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 will 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 proposed to continue this pattern for each subsequent year beyond CY 2013, considering OASIS assessments submitted for episodes beginning 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 June 30 of the calendar year one year prior to the calendar year of the APU effective date, and received timely by CMS (that is, within 30 days of the end of that time period), as fulfilling the OASIS portion of the quality reporting requirement for the subsequent APU.

Comment: We received one comment which supported both of these proposals. We received no comments in opposition.

Response: We appreciate the supportive comments.

As a result of the comments received, we are finalizing these two proposals as proposed.

(2) Acute Care Hospitalization Claims-Based measure

In August 2003, we began to publicly report on Home Health Compare a number of OASIS–C outcome measures, including Acute Care Hospitalization. Since that time, we have determined that claims data are a more robust source of data for accurately measuring acute care hospitalizations. For this reason we proposed 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.

At the time of the publication of the proposed rule, there were technical issues with Home Health Compare files which resulted in our plan to delay the reporting of the two claims-based measures ''Emergency Department Use Without Hospitalization'' and ''Acute Care Hospitalization'' until such time as the technical issues were resolved. We stated that the OASIS-based Acute Care Hospitalization measure would 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 proposed 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.

Comment: We received nine comments supportive of the proposal and the use of claims-based measures in general. One commenter clearly prefers the OASIS-based Acute Care Hospitalization measure, stating it provides more granularity. Two commenters opposed publicly reporting the claims-based Acute Care Hospitalization measure until measure specifications and measure detail are made available and requested to preview the measure before public reporting. Several commenters question how observation stays will be addressed in the measure. We also received comment regarding the restriction of claims-based measures to Medicare FFS patients, the need to harmonize with other reporting programs, the need to retain OASIS items related to these two measures, and the resolution of technical issues referenced in the proposed rule.

Response: We have resolved the technical challenges that we noted in the proposed rule and in August, the CASPER reports included Acute Care Hospitalization and Emergency Department Use Without Hospitalization measure rates that we calculated using claims data. We will also begin to publicly report the claims-based measure rates for these measures on Home Health Compare.

We wish to clarify that when we referred to the Acute Care Hospitalization and Emergency Department Use Without Hospitalization measures as ''replacing'' the OASIS-based measures, what we meant is that the measures will be calculated using a new source of data. The measure concept has not changed. The revised technical specifications were provided to the National Quality Forum (NQF), and after a public comment period, the NQF endorsed the revised measures in August 2012. The Acute Care Hospitalization measure is NQF #0171 and the ED Use Without Hospitalization measure is NQF #0173. The technical specifications for the claims-based measures been available since September 12 on the CMS Home Health Quality Initiative web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

HHAs can currently view their performance on both measures (calculated using claims data) on their agency-specific CASPER reports. To further respond to the commenters who requested more detail on the measures, these measures evaluate the utilization of emergency department use without hospitalization and acute care hospitalization during the 60 days after the start of the home health stay. Thus, the measures address outcomes of HHA patients in a fixed interval after the start of their home health care, regardless of the length of their home health stay. Home health agencies are most often paid in a 60-day payment bundle which covers all home health services for 60 days. As a result, the claims-based measures address outcomes of home health patients during the time period in which their home health agency receives payment from Medicare, (that is, for the 60-day period beginning with the start of care date). This is in contrast to the OASIS-based measures which calculate outcomes based on the time period from start of care to discharge, a period which may be greater or less than 60 days.

Similarly, the measurement begins at home health start of care (rather than at hospital discharge) as the home health agency cannot be held responsible for hospitalizations or emergency department visits that occur before home health care begins. Home Health Compare will continue to display these

measures using a rolling twelve months of data updated on a quarterly basis.

As with the OASIS-based measure, planned hospitalizations are excluded from the acute care hospitalization claims-based measure numerator. In addition, though some hospitalizations may be avoidable, it is difficult to determine if a hospitalization was out of the home health agency's control or not. As a result, agency rates on this measure are not expected to reach zero percent. Instead, the measure rates can be used as guidelines for comparing agencies to each other and can be used by agencies to improve their quality of care.

Observation stays that begin in a hospital emergency department but do not result in an inpatient stay within the 60 days after the start of home health care are counted in the ED Use without Hospitalization measure. Observation stays that result in an inpatient stay within the 60 days after the start of home health care are counted in the Acute Care Hospitalization measure. By comparing HHAs on both utilization measures, consumers can gain an accurate picture of how often patients of each HHA receive care in an emergency department or hospital in the 60 days following the start of home health care.

Medicare claims data are reliable because home health agencies are required to submit claims in order to receive payment for Medicare beneficiaries. Claims data are extremely detailed and include patient identifiers, provider identifiers, services rendered, diagnoses, and payment, as well as additional information. Because encounter claims data are only readily available for Medicare FFS beneficiaries, the measure rates generated from claims for both the Acute Care Hospitalization and Emergency Department Use Without Hospitalization measures will only reflect Medicare FFS data.

We are considering whether to begin calculating other OASIS–C outcome measures using claims data and we are also considering the feasibility of proposing to adopt readmission measures, which might include a 30-day measure of rehospitalization that would apply to home health patients who begin home health immediately after an inpatient hospital stay. We note that this measure would be similar to ''Hospital-Wide All-Cause Unplanned Readmission'' measure that we recently adopted for the Hospital Inpatient Quality Reporting Program.

We believe that the OASIS items related to acute care hospitalization and emergency department use should remain in the OASIS dataset. It is important for agencies to be aware of their patient's hospitalizations and emergency department visits in order to adjust care plans in response to changes in the patient's condition, medication regimen, and care needs. Maintaining the items in the OASIS also allows agencies to monitor their hospitalization and ED use rates in real-time rather than waiting for a claims-based measure to be calculated and reported in CASPER. The OASIS item related to emergency department use is still used for the Emergency Department Use With Hospitalization measure reported on CASPER. Agencies can approximately compare their rates on the OASIS-based and claims-based Acute Care Hospitalization measures, as reported on the CASPER reports, to gauge if their patients received treatment in an emergency department or hospital significantly more often than they were aware of. This comparison could be useful in HHAs' performance improvement activities.

As a result of the comments received, we are finalizing that the claims-based Acute Care Hospitalization measure replace the OASIS-based measure on Home Health Compare as proposed.

d. Home Health Care CAHPS Survey (HHCAHPS)

In the HH PPS Rate Update for CY 2012 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.

(1) 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) (number 0517). The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The 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 of the three composite measures consists of four or more questions on 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 a 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, which are paid for by Medicare or Medicaid.

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

- Are under the age of 18;
- Are deceased prior to 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.*

(2) HHCAHPS Oversight Activities

We stated in prior final rules that vendors 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 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 proposed to codify the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities at § 484.250(c) of our regulations.

(3) HHCAHPS Requirements for CY 2014

For the CY 2014 APU, we proposed to continue monthly HHCAHPS data collection and reporting for four quarters. The data collection period for CY 2014 would include the second quarter 2012 through the 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.

We would 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 proposed to maintain this stated exemption for new HHAs.

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.

(4) HHCAHPS Requirements for CY 2015

For the CY 2015 APU, we proposed to continue to require the continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for CY 2015 would include the second quarter 2013 through the 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 proposed to continue to exempt HHAs receiving Medicare certification on or after April 13, which is 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 are not 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 proposed to maintain this stated exemption for new HHAs.

Likewise, 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.

(5) 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.

(6) Summary of Proposed Changes in CY 2013

We proposed one change in the CY 2013 HH PPS proposed rule issued in the July 13, 2012 **Federal Register** (77 FR 41548). We proposed to codify the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities, and include this at § 484.250(c).

(7) 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.

The following is a summary of the comments we received regarding the Home Health Care CAHPS Survey (HHCAHPS) proposal.

Comment: We received several comments that expressed confusion over CMS's statement that we would codify the HHCAHPS guideline that home health agencies ensure that survey vendors are fully compliant with all HHCAHPS requirements because vendors are approved by CMS. These commenters noted that an agency should accept CMS's approval as verification that the vendor meets all HHCAHPS requirements and should not be held responsible for any compliance failures of a CMS-approved vendor.

Response: In the proposed rule, we proposed to codify the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We proposed to include this survey requirement at § 484.250(c). This was correct. However, we were not clear in the proposed rule about the HHA's role. HHAs do not need to participate in vendor oversight activities. We have corrected this in the final rule. We have clarified this language in the preamble of the final rule based on comments, that the HHCAHPS approved vendors have to comply with HHCAHPS oversight activities. We in error noted in the preamble of the proposed rule that HHAs have to comply with HHCAHPS oversight activities. However, HHAs are responsible for monitoring their vendors to ensure that vendors submit their data on time, using the information that is available to them on the HHCAHPS data submission reports accessible through *https://homehealthcahps.org.* If we become aware of a significant vendor issue that would put HHAs at risk for not meeting the APU requirements, we will immediately alert the affected HHAs. If we find that a vendor does not comply with HHCAHPS protocols and guidelines, or correct in a timely manner any deficiencies that are found during oversight activities, then we will remove that vendor from the approved list of HHCAHPS survey vendors.

Comment: One commenter believed that there needs to be enough flexibility within the reconsideration process to provide relief to HHA providers that have made reasonable efforts to ensure that their survey vendors have complied with the HHCAHPS requirements.

Response: We review each HHA submission for the reconsideration process in a standardized manner so that all HHAs are treated fairly in the review process. If we become aware of a significant vendor issue that would put HHAs at risk for not meeting the APU requirements, we will immediately alert the affected HHAs. If we find that a vendor does not comply with HHCAHPS protocols and guidelines, or correct in a timely manner any deficiencies that are found during oversight activities, then we will remove that vendor from the approved list of HHCAHPS survey vendors.

Comment: One commenter stated that there is continued concern that the HHCAHPS survey places another unfunded administrative burden on HHAs—a mandate that requires significant time to work with CMS's approved vendor selected by the HHA provider.

Response: The collection of the patient's perspectives of care data for similar CAHPS surveys, such as Hospital CAHPS, follow the same model where providers pay the approved survey vendors for the data collection, and CMS pays for the HHCCAHPS survey vendor training, technical support and assistance for HHAs and for HHCAHPS survey vendors, oversight of HHCAHPS survey vendors, and data analysis of the HHCAHPS survey data. HHAs are strongly encouraged to report their respective HHCAHPS costs on their cost reports but should note that the HHCAHPS costs are not reimbursable under the HH PPS. We encourage HHAs to ''shop around'' for the best cost value for them before contracting with an approved HHCAHPS vendor to conduct the survey on their behalf.

Comment: We received a comment requesting that CMS consider reporting the percent of patients that would probably recommend this agency to family and friends, in addition to reporting the percent of patients that

would definitely recommend this agency to family and friends.

Response: Thank you for your feedback. We will take it under consideration.

Comment: We received a comment that is in full support of the HHCAHPS and would suggest that CMS continue to report updates on HHCAHPS in the open door forums. Also, this commenter said that it might be very helpful to include HHCAHPS as a scope of work with the QIOs so that best practices to increase consumer satisfaction could be established and shared.

Response: We appreciate supportive comments about HHCAHPS. The survey provides an opportunity for patients to share their perspectives about the care provided. We appreciate your suggestion to include HHCAHPS in the SOW for the QIOs and will take it under consideration.

We are finalizing the proposed requirements for HHCAHPS as proposed in the CY 2013 HH PPS proposed rule. We are also codifying the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We are including this at § 484.250(c). The regulation is identically stated in the proposed rule and in this final rule.

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. In the CY 2013 HH PPS proposed rule (77 FR 41548), as in previous years, we proposed 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 inpatient prospective payment system (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*

The following is a summary of the comments we received regarding the wage index policy in the CY 2013 HH PPS proposed rule.

Comment: Commenters expressed concern about the inequities between the hospital wage index and the home health wage index. Several commenters believed that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting home health costs. Commenters cited labor market distortions created by reclassification of hospitals in areas in which HHAs are not reclassified. However, while hospitals have the opportunity to reclassify to neighboring CBSAs or take advantage of the rural floor, HHAs do not have this ability. Commenters stated that this has resulted in inadequate home health cost adjustment that negatively impact HHAs ability to recruit and retain nurses and therapists in a highly competitive health care labor market. CMS's reasoning for refusing to apply reclassification to HHAs is that reclassification applies only to hospitals by statute. However, if hospital relative wages are thought to be a reasonable proxy for relative wages of HHAs, the impact of hospital reclassifications in an area should be applied to the hospital wage index which in turn is applied to the home health reimbursement.

Response: As we have previously stated (see the CY 2009 HH PPS final rule at 74 FR 58105), the regulations that govern the HH PPS do not provide a mechanism for allowing providers to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. The rural floor provision can be found in section 4410 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) and is specific to hospitals. The reclassification provision can be found in section 1886(d)(10) of the Act is also specific to hospitals. In its June 2007 report titled, ''Report to Congress: Promoting Greater Efficiency in Medicare'', MedPAC recommended that Congress ''repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems.'' We will continue to review and consider MedPAC's recommendations on a refined alternative wage index methodology for the HH PPS in the future.

Comment: A commenter believes that CMS's decision 7 years ago to switch from Metropolitan Statistical Areas to Core-Based Statistical Areas for the wage index calculation has had serious financial ramifications for HHAs in certain areas.

Response: We believe that adjusting payments based on the CBSA areas is the best available method of compensating for differences in labor markets. We adopted the OMB-revised definitions of the labor market areas (CBSAs) in our CY 2006 HH PPS final rule (70 FR 68137). We implemented a one-year transition policy consisting of a 50/50 blend of the MSA-based and the new CBSA-based wage indexes for that year. The HH PPS has been utilizing the

CBSA based wage index in its entirety since calendar year 2007.

Comment: Several commenters stated that the year-to-year swings in the wage index are unpredictable. Commenters also urged CMS to implement a policy to limit the wage index variation between provider types within CBSAs and adjacent markets. Commenters suggested that CMS establish ''change corridors'' to limit the annual change in wage index values in a given year.

Response: Updating the hospital wage index is done in a budget neutral manner. Establishing ''change corridors'' or limits on how much a particular wage index could increase or decrease from year-to-year would not be consistent with budget neutrality.

Comment: A commenter stated that the wage index is often based on inaccurate or incomplete hospital cost report data.

Response: We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our intermediaries perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. Furthermore, HHAs have the opportunity to submit comments on the hospital wage index data during the annual IPPS rulemaking period. Therefore, we believe our review processes result in an accurate reflection of the applicable wages for the areas given.

Comment: Several commenters supported a review of the entire wage index system and urge CMS to expedite that review and implement a system that not only recognizes variations between localities, but also treats all provider types within a local market equitably.

Response: Two studies were undertaken to address concerns that the current wage index system does not effectively reflect the true variation in labor costs. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to the Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies recently have been released. We refer readers to the FY 2013 IPPS final rule for summaries of the studies, their findings, and recommendations on reforming the wage index system (77 FR 28116).

Comment: A commenter stated that differences in the occupational personnel pool and costs between hospitals and HHAs make use of the hospital wage index inappropriate in the home health setting. Hospitals benefit from institutional efficiencies and rural hospitals have a reclassification mechanism to avoid exposure to the drastic rural rate in most states. Despite repeated comments from HHAs opposing the use of the hospital wage index each year, CMS has not yet developed a home health specific wage index, citing the expense and administrative burden of data collection. The commenter stated that CMS has the discretion to establish a home health wage index and that the use of the hospital wage index to adjust non-hospital reimbursement rates was originally intended to be an interim measure while CMS examined industry-specific wage data for HHAs, SNFs, IRFs and other post-acute services. The commenter cited the following rules: 65 FR 41127 (July 12, 2000), 65 FR 46770 (July 31, 2000), and 66 FR 41316 (August 7, 2001).

Response: Please note that the July 31, 2000 rule (65 FR 46770) is a SNF rule and the August 7, 2001 rule (66 FR 41316) is an IRF rule so they do not apply to the HH PPS. The HH PPS rule at 65 FR 41127 was published on July 3, 2000 and we did not intend or imply that our adoption of the pre-floor, pre-reclassified hospital wage index to be an interim measure. As we stated in the July 3, 2000 HH PPS final rule (65 FR 41173), ''To be consistent with the wage index adjustment under the current interim payment system, we proposed and will retain applying the appropriate wage index value to the labor portion of the PPS rates based on the geographic area in which the beneficiary received home health services.'' We further noted that ''In establishing the final HHA PPS rates, we used the most recent pre-floor, pre-reclassified hospital wage index without regard to whether these hospitals have been reclassified to a new geographic area by the Medicare Geographic Reclassification Board.'' As stated above, we refer readers to the FY 2013 IPPS Final Rule (77 FR 28116) for summaries of the two studies undertaken to address concerns that the current hospital wage index system does not effectively reflect the true variation in labor costs, their findings, and recommendations on reforming the wage index system.

Comment: A commenter noted that beginning in FY 2004, CMS dropped critical access hospitals (CAHs) from the calculation of the wage index. As CAHs are located in rural areas, the absence of CAH wage data further compromises the accuracy and appropriateness of using hospital wage data to determine labor costs of HHAs located in rural areas.

Response: Although the pre-floor, pre-reclassified hospital wage index data does not include CAHs, we believe it most appropriately reflects the relative level of wages and wage-related costs applicable to the furnishing of home health services and provide appropriate adjustments to the episode payment amounts under the HH PPS to account for area wage differences. Therefore, for this final rule, we are adopting the pre-floor, pre-reclassified hospital wage index.

Comment: A commenter suggested, pending development of an industry specific wage index, that CMS should investigate adding a population density factor to the calculation of the payment formula. This would provide incentive to HHAs to service beneficiaries residing in low density (primarily rural) areas, while at the same time reducing excess reimbursement for services provided in densely populated urban and congregate living facilities. The commenter states that travel time and mileage costs incurred for providing home health services to patients that are grouped in the lowest population density group is more than double that of the highest population density group.

Response: We have received and responded to this comment in prior rules. We appreciate the commenter's comment, but we do not have evidence that a population density adjustment is an appropriate adjustment to a wage index. Section 3131(d) of the Affordable Care Act requires the Secretary to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved

areas, and in treating beneficiaries with varying levels of severity of illness. Because medically underserved areas may be associated with population density, the purview of the above mentioned study may possibly include feasibility of such an adjustment as part of that research. While rural agencies cite the added cost of long distance travel to treat their patients, urban/non-rural agencies also cite added costs such as needed security measures and the volume of traffic that they must absorb. We will consider this suggestion in future research activities.

Comment: A commenter requested that the county in which its HHA is located be reclassified into a different CBSA. The commenter believes that the ability to attract and retain qualified competent health care professionals will be adversely affected if the county is not reclassified into another CBSA.

Response: We adopted the OMB-revised definitions of the labor market areas (CBSAs) in our CY 2006 HH PPS final rule (70 FR 68137). We implemented a one-year transition policy consisting of a 50/50 blend of the MSA-based and the new CBSA-based wage indexes. The HH PPS has been utilizing the CBSA based wage index in its entirety since calendar year 2007. We do not have the authority to redesignate a county into a different CBSA.

We are implementing our proposal 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.

5. Final 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 are finalizing 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 final 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.

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 update the national per-visit rates by discipline annually by the applicable home health market basket percentage. We 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. For CY 2013, we proposed 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 will update the LUPA add-on payment amount and the NRS conversion factor by the applicable home health payment update of 1.3 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 (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. Final Updated CY 2013 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2013 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 final CY 2013 home health payment update of 1.3 percent.

As previously discussed in section III.A. (''Case-Mix Measurement'') of this final rule, we have updated our analysis of the change in case-mix that is not due to an underlying change in patient health status. The analysis revealed an additional increase in nominal change in case-mix, increasing the reduction needed in CY 2013 to fully account for nominal case-mix change from 1.32 percent, using data through 2009, to 2.18 percent, using data through 2010. However, we will reduce rates by 1.32 percent in CY 2013 as promulgated in the CY 2012 HH PPS Final Rule. 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 final CY 2013 national standardized 60-day episode payment rate for an HHA that submits the required quality data is

shown in Table 12. The final CY 2013 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the final CY 2013 home health payment update (1.3 percent) minus 2 percentage points and is shown in Table 13.

TABLE 12: CY 2013 National 60-Day Episode Payment Amount

CY 2012 National Standardized 60-Day Episode Payment Rate	Multiply by the CY 2013 home health payment update of 1.3 percent	Reduce by 1.32 percent for nominal change in case-mix	CY 2013 National Standardized 60-Day Episode Payment Rate.
$2,138.52	X 1.013	X 0.9868	$2,137.73

TABLE 13: For HHAs that Do Not Submit the Quality Data –CY 2013 National 60-Day Episode Payment Amount

CY 2012 National Standardized 60-Day Episode Payment Rate	Multiply by the CY 2013 home health payment update of 1.3 percent minus 2 percentage points (-0.7 percent)	Reduce by 1.32 percent for nominal change in case-mix	CY 2013 National Standardized 60-Day Episode Payment Rate.
$2,138.52	X 0.993	X 0.9868	$2,095.52

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 final CY 2013 home health payment update of 1.3 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit 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 14.

TABLE 14: CY 2013 National Per-Visit Payment Amounts

		For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
Home Health Discipline Type	CY 2012 Per-Visit Amounts Per 60-Day Episode	Multiply by the CY 2013 payment update of 1.3 percent	CY 2013 per-visit payment	Multiply by the CY 2013 payment update of 1.3 percent minus 2 percentage points (-0.7 percent)	CY 2013 per-visit payment
HH Aide	$51.13	X 1.013	$51.79	X 0.993	$50.77
MSS	$180.96	X 1.013	$183.31	X 0.993	$179.69
OT	$124.26	X 1.013	$125.88	X 0.993	$123.39
PT	$123.43	X 1.013	$125.03	X 0.993	$122.57
SN	$112.88	X 1.013	$114.35	X 0.993	$112.09
SLP	$134.12	X 1.013	$135.86	X 0.993	$133.18

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 CY 2013 home health payment update of 1.3 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, the add-on to the LUPA payment for HHAs that submit the required quality data will be updated by the CY 2013 home health payment update of 1.3 percent. The CY 2013 LUPA add-on payment amount is shown in Table 15. The add-on to the LUPA payment for HHAs that do not submit the required quality data will be updated by the CY 2013 home health payment update (1.3 percent) minus two percentage points.

TABLE 15: CY 2013 LUPA Add-On Amounts

	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
CY 2012 LUPA Add-On Amount	Multiply by the CY 2013 payment update of 1.3 percent	CY 2013 LUPA Add-On Amount	Multiply by the CY 2013 payment update of 1.3 percent minus 2 percentage points (-0.7 percent)	CY 2013 LUPA Add-On Amount
$94.62	X 1.013	$95.85	X 0.993	$93.96

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 payment update of 1.3 percent. The final updated CY 2013 NRS conversion factor for 2013 appears in Table 16.

TABLE 16: CY 2013 NRS Conversion Factor for HHAs that DO Submit the Required Quality Data

CY 2012 NRS Conversion Factor	Multiply by the CY 2013 payment update of 1.3 percent	CY 2013 NRS Conversion Factor
$53.28	X 1.013	$53.97

Using the NRS conversion factor ($53.97) for CY 2013, the payment amounts for the various severity levels are shown in Table 17.

TABLE 17: CY 2013 NRS Payment Amounts for HHAs that DO Submit the Required Quality Data

Severity Level	Points (Scoring)	Relative Weight	CY 2013 NRS Payment Amount
1	0	0.2698	$14.56
2	1 to 14	0.9742	$52.58
3	15 to 27	2.6712	$144.16
4	28 to 48	3.9686	$214.19
5	49 to 98	6.1198	$330.29
6	99+	10.5254	$568.06

For HHAs that do not submit the required quality data, we again begin with the CY 2012 NRS conversion factor. We increase the CY 2012 NRS conversion factor ($53.28) by the CY 2013 home health payment update of 1.3 percent minus 2 percentage points. The CY 2013 NRS conversion factor for

HHAs that do not submit quality data is shown in Table 18.

TABLE 18: CY 2013 NRS Conversion Factor for HHAs that DO NOT Submit the Required Quality Data

CY 2012 NRS Conversion Factor	Multiply by the CY 2013 payment update of 1.3 percent minus 2 percentage points (-0.7 percent)	CY 2013 NRS Conversion Factor
$53.28	X 0.993	$52.91

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 19.

TABLE 19: CY 2013 NRS Payment Amounts for HHAs that DO NOT Submit the Required Quality Data

Severity Level	Points (Scoring)	Relative Weight	NRS Payment Amount
1	0	0.2698	$14.28
2	1 to 14	0.9742	$51.54
3	15 to 27	2.6712	$141.33
4	28 to 48	3.9686	$209.98
5	49 to 98	6.1198	$323.80
6	99+	10.5254	$556.90

6. Rural Add-On

Section 421(a) of the MMA required, for home health services furnished in a rural areas (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 20 through 24 for these payment rates.

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TABLE 20: 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		
CY 2013 National Standardized 60-Day Episode Payment Rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 National Standardized 60-Day Episode Payment Rate	CY 2013 National Standardized 60-Day Episode Payment Rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 National Standardized 60-Day Episode Payment Rate
$2,137.73	X 1.03	$2,201.86	$2,095.52	X 1.03	$2,158.39

TABLE 21: CY 2013 Per-Visit Amounts for Services Provided in a Rural Area

	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
Home Health Discipline Type	CY 2013 per-visit rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 per-visit rate	CY 2013 per-visit rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 per-visit rate
HH Aide	$51.79	X 1.03	$53.34	$50.77	X 1.03	$52.29
MSS	$183.31	X 1.03	$188.81	$179.69	X 1.03	$185.08
OT	$125.88	X 1.03	$129.66	$123.39	X 1.03	$127.09
PT	$125.03	X 1.03	$128.78	$122.57	X 1.03	$126.25
SN	$114.35	X 1.03	$117.78	$112.09	X 1.03	$115.45
SLP	$135.86	X 1.03	$139.94	$133.18	X 1.03	$137.18

TABLE 22: 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		
CY 2013 LUPA Add-On Amount	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 LUPA Add-On Amount	CY 2013 LUPA Add-On Amount	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 LUPA Add-On Amount
$95.85	X 1.03	$98.73	$93.96	X 1.03	$96.78

TABLE 23: 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		
CY 2013 Conversion Factor	Multiply by the 3 Percent Rural Add-On	Rural CY 2013 Conversion Factor	CY 2013 Conversion Factor	Multiply by the 3 Percent Rural Add-On	CY Rural 2013 Conversion Factor
$53.97	X 1.03	$55.59	$52.91	X 1.03	$54.50

TABLE 24: CY 2013 NRS Payment Amounts for Services Provided in Rural Areas

		For HHAs that **DO** submit quality data (NRS Conversion Factor=$55.59)		For HHAs that DO **NOT** submit quality data (NRS Conversion Factor=$54.50)	
Severity Level	Points (Scoring)	Relative Weight	Total NRS Payment Amount for Rural Areas	Relative Weight	Total NRS Payment Amount for Rural Areas
1	0	0.2698	$15.00	0.2698	$14.70
2	1 to 14	0.9742	$54.16	0.9742	$53.09
3	15 to 27	2.6712	$148.49	2.6712	$145.58
4	28 to 48	3.9686	$220.61	3.9686	$216.29
5	49 to 98	6.1198	$340.20	6.1198	$333.53
6	99+	10.5254	$585.11	10.5254	$573.63

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The following is a summary of the comments we received regarding the HH PPS payment rates.

Comment: Commenter supports the continuation of the rural add-on and CMS's recognition of the challenges faced by rural providers.

Response: We value the crucial role that rural providers fill in providing care to beneficiaries who reside in rural areas. The current rural add-on is legislated by 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 for episodes and visits ending on or after April 1, 2010 and before January 1, 2016.

Comment: A commenter urges CMS to consider a 5 percent rural add-on.

Response: To bolster payment rates for services provided to beneficiaries who reside in rural areas, section 421(a) of the MMA, as amended by section 3131(c) of the Affordable Care Act, provides for a 3 percent rural add-on 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. The amount of the rural add-on is stipulated by section 421(a) of the MMA.

Comment: A commenter believes that HHAs that serve beneficiaries in rural areas are in a particularly precarious financial situation. The commenter stated that rural HHAs operating costs are higher than urban HHAs. In addition, the commenters are concerned about access to care for rural beneficiaries. One commenter goes on to state that rural HHAs often function as the primary caregivers for elderly homebound patients who have high resource needs which also increase the cost of rural home health services.

Response: As we stated above, we value the crucial role that rural providers fill in providing care to beneficiaries who reside in rural areas. We will be looking to improve the accuracy of payment to HHAs in the future, through a number of efforts. In particular, section 3131(d) of the Affordable Care Act requires the Secretary to study and report on the development of HH payment revisions that would ensure access to care and payment for severity of illness. The study is to be on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. As part of this study, we are required to consult with appropriate stakeholders, such as groups representing HHAs and groups representing Medicare beneficiaries. At the conclusion of this study, we must submit a Report to the Congress by March 1, 2014. Based on the findings of this study, the Secretary may provide for a demonstration project to test whether making payment adjustments for HH services under the Medicare program would substantially improve access to care for patients with high severity levels of illness or for low-

income or underserved Medicare beneficiaries.

We are implementing the payment rates as they appear in sections III.C.5 and III.C.6 above.

D. Home Health Face-to-Face Encounter

1. Additional 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, sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, as amended by the Affordable Care Act state 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, that the 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 suggested 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. We do not believe the statute precludes this situation from occurring. Therefore, in the CY 2013 HH PPS proposed rule (77 FR 41548)), for patients admitted to home health from an acute or post-acute facility we proposed 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.

The following is a summary of the comments we received regarding the additional flexibility proposed.

Comment: Most commenters expressed support of the additional flexibility proposed. One commenter stated that the proposal will be difficult to implement and educate physicians on and that physicians often do not want to certify based on information provided to them from a different physician or allowed NPP.

Response: We thank the commenters for their support and acknowledge since the implementation of the face-to-face encounter requirements in CY 2011 (75 FR 70372) we have heard that many HHAs and practitioners believe that the requirements are confusing and hard for providers to understand. As result, we recently released a revised set of Q&As and a MLN Matters article. We created this guidance with the goal of increasing the understanding of the face-to-face requirements among physicians and to provide additional flexibilities that certifying physicians can utilize in completing the face-to-face encounter documentation. For example, if the certifying physician is hesitant to use information provided to them from another physician or allowed NPP, the certifying physician can use a hospital's discharge summary as the face-to-face documentation as long as it is clearly titled and dated as such, and contains all the documentation requirements and is signed by the certifying physician. The Q&As are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/QandAsFull-revised-062712.pdf* and the MLN Matters article is available at: *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1219.pdf*.

Comment: One commenter recommended that CMS permit allowed NPPs in the acute or post-acute setting to speak directly with the certifying physician about the patient's clinical and homebound status and need for skilled care. Another commenter recommended that CMS allow the physician to sign off on the NPP's clinical findings and permit the NPP to send his or her clinical findings with the physician signature directly to the certifying physician. The commenter also stated that HHAs should not have to ensure that the acute or post-acute care physician is the supervising physician of the NPP that performed the face-to-face encounter.

Response: In the acute or post-acute care setting, current policy permits allowed NPPs to perform the face-to-face encounter and directly inform the certifying physician of the clinical findings and how such findings support that the patient is homebound and needs skilled services. It would also be permissible for the physician in the acute or post-acute care facility that cared for the patient in that setting to sign off on the NPPs clinical findings, which would be sent to the certifying physician by the NPP who is collaborating directly with the certifying physician. However, it is still the responsibility of the certifying physician to document the date that the face-to-face encounter occurred and that the condition for which the patient was being treated in the face-to-face encounter is related to the primary reason the patient requires home health services and that the clinical findings of the encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services. Likewise, the completion of the face-to-face encounter documentation is required to be completed by the physician that is certifying the patient for home health services, rather than the HHA. As such, the certifying physician should only be documenting an actual face-to-face encounter that was performed by an allowed NPP or the physician that cared for the patient in the acute or post-acute care setting as defined in § 424.22(a)(1)(v) in satisfying the face-to-face encounter requirements.

Comment: One commenter expressed concern that claims could be denied because the communication between the acute or post-acute care physician and the community certifying physician

might not be evident as it could occur via telephone or in person (rather than via email or written correspondence).

Response: It is the responsibility of the certifying physician to document that the face-to-face encounter occurred and to satisfy the content requirements. It would be acceptable for the certifying physician to obtain information verbally either from a physician in the acute or post-acute care facility that cared for the patient in that setting, or an allowed NPP who is either collaborating directly or under the supervision of either the certifying physician or the physician who cared for the patient in the acute or post-acute care setting, and document what was conveyed orally as long as all the content requirements are met.

Comment: Some commenters stated that the face-to-face encounter documentation requirements create substantial burden for HHAs in ensuring documentation compliance. Often times, physicians are confused as to what is required of them, view the paperwork as duplicative, and are uncooperative, which cause significant resources being invested by the HHA into obtaining the required documentation. Further, if the face-to-face encounter documentation is not obtained, the HHA is penalized for physician noncompliance. One commenter stated that electronic medical records and meaningful use standards should result in the information being readily available to support the patient's homebound status and need for skilled services, negating the need for a separate documentation requirements. Other commenters suggested that CMS allow a signed and dated discharge summary or physician's office note to stand as evidence of the face-to-face encounter, and one commenter questioned why it was necessary to document a face-to-face encounter when a patient was admitted from an acute or post-acute care setting, as the patient was obviously under the care of a physician during his or her stay. Moreover, several commenters asked CMS to rescind our face-to-face encounter documentation requirements or allow providers to bill for Medicare eligible services when the physician does not comply with completing the face-to-face documentation. Finally, some commenters suggested that if the face-to-face documentation is not provided by the certifying physician to the HHA within 5 days of referral, the HHA would provide a Home Health Advance Beneficiary Notice (HHABN) Option 2 at that time.

Response: We thank the commenters for their comments, but these comments are outside the scope of this rule. However, we would like to remind commenters that we do not have the authority to rescind the requirement for certifying physicians to document the face-to-face encounter, nor exempt HHAs from responsibility for the face-to-face encounter requirements regardless of the setting from which the patient was admitted or for physician noncompliance, as section 6407 of the Affordable Care Act mandates it is a condition for payment. As we stated above, a recently revised set of Q&As and a MLN Matters article were released, which specify certain flexibilities that certifying physicians can utilize in completing the face-to-face encounter documentation. For example, the certifying physician can use the discharge summary as the face-to-face documentation as long as it is clearly titled and dated as such, and contains all the documentation requirements and is signed by the certifying physician. In response to commenters who suggested that an HHABN Option 2 be delivered to the patient if the face-to-face encounter documentation is not provided by the certifying physician to the HHA within 5 days, HHAs may issue an HHABN Option 2 to the patient after only 5 days; however, the current regulations at § 424.22(a)(1)(v) allow a face-to-face encounter to occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and HHAs should recognize that they are responsible for providing information to Medicare beneficiaries prior to the start of care about the extent to which Medicare may pay for services and thereafter prior to a change in payment status under the Patient Rights Condition of Participation set out in § 484.10(e). We want to reiterate that the HHABN Option 2 does not transfer liability to the beneficiary when technical requirements for payment, such as the face-to-face encounter documentation, are not met.

Comment: Several commenters requested that, due to difficulties in obtaining face-to-face encounter documentation from physicians, the face-to-face documentation requirements should be limited to the date which the encounter occurred and that the condition for which the patient was being treated in the face-to-face encounter is related to the primary reason the patient requires home health services. Some commenters suggested that CMS allow the preprinted certification statement (from the former CMS 485/plan of treatment) to suffice as documentation of the patient's homebound status. In addition, several commenters suggested that CMS allow a ''non-PCP specialist'' medical director to sign the face-to-face encounter documentation, allow additional types of practitioners to conduct the face-to-face encounter, allow an HHA's Medical Director to complete the face-to-face encounter, including documentation of such encounter, and permit allowed NPPs and other types of practitioners to certify patients for home health services. Other commenters suggested that CMS allow physicians to delegate the documentation requirements to allowed NPPs.

Response: Some of these comments are outside the scope of this rule. However, we would like to respond to the comments that request CMS not to require the face-to-face documentation to contain why the clinical findings of such encounter support that the patient is homebound and in need of intermittent skilled nursing services or therapy services or that we allow a preprinted statement from the former CMS 485/plan of treatment to suffice as documentation of the patient's homebound status. As we stated in the CY 2011 final rule implementing the face-to-face encounter documentation requirements (76 FR 68594), using the words ''document the encounter'' in the statute instead of ''attest to the encounter'' suggests that the Congress intended the face-to-face encounter documentation to include factual information about the patient's condition as seen during the encounter which would support the physician's certification of the patient's eligibility for home health services (that is, homebound status and need for skilled services). Likewise, as the statute requires the certifying physician to document the face-to-face encounter, it would not be permissible to delegate this responsibility to an allowed NPP or to use preprinted statements. In response to the comments suggesting that additional types of practitioners, an HHA Medical Director, or a ''non-PCP specialist'' MD should be able to conduct and/or document the face-to-face encounter, we do not have the authority to further define the types of practitioners allowed to perform the face-to-face encounter and because documentation of a the face-to-face encounter is required for certification, the certifying physician is responsible for documenting the face-to-face encounter. In addition, we do not have the statutory authority to permit allowed NPPs or other types of practitioners to certify patients for home health services, nor is it permissible for

HHA Medical Directors to certify patients for home health services, of which the face-to-face encounter documentation is one component, as longstanding regulations at § 424.22 impose financial restrictions on the relationship between an HHA and the certifying physician. The face-to-face encounter provision in the Affordable Care Act was designed as an anti-fraud provision and CMS is committed to ensuring that Medicare reimbursement is available only to patients actually in need of home health services.

Comment: Some commenters asked that we further define ''exceptional circumstances'' in which the face-to-face encounter can be waived to include circumstances where the patient moves, changes physician, or is re-hospitalized within 30 days of the start of the home health episode. Several commenters also asked that CMS expand the window of time during which a face-to-face encounter can occur to 60 days after admission to home health. Other commenters stated that many beneficiaries that are homebound and/or live in remote areas are not able to travel to their doctor's offices or have limited transportation options to satisfy the face-to-face encounter requirements and some commenters suggested that Medicare reimburse for the expense of a non-urgent stretcher or wheelchair transport to a physician's office to fulfill the face-to-face encounter requirements, while others suggested that CMS allow individuals to meet the face-to-face encounter requirements through telehealth technologies that could be made available in patient's homes.

Response: Some of these comments are outside the scope of this rule. We will consider the commenters suggestions on further defining ''exceptional circumstances'' in which face-to-face encounter requirements could be waived for future rulemaking. However, we will take the opportunity to briefly respond to some of the commenters' other concerns. Regarding the timeframe allowed to conduct the face-to-face encounter, we believe the current timeframe of 90 days prior to the start of care and 30 days after the start of care is appropriate and best meets the needs of program integrity efforts and quality goals associated with the provision. For those patients that are homebound and require non-urgent stretcher or wheelchair transport to reach the physician's office, we do not have the statutory authority to reimburse for these services under the Medicare home health benefit as they are not defined as ''home health services'' according to section 1861(m) of the Act. In response to allowing telehealth in patient's home, we note that section 1834(m) of the Act limits the provision of telehealth services to certain originating sites where the service can be provided.

Comment: Several commenters asked CMS to review its claims data to determine whether the implementation of the face-to-face encounter requirements has impacted access to care.

Response: We have conducted analyses looking at the number of paid claims, both nationally and by state, for 2009 through 2011. Our analyses show that face-to-face requirements have not had an adverse effect on access to Medicare HH services as the volume of paid claims is consistent with previous years.

After carefully considering all of the comments received, we are finalizing the additional flexibility as proposed. We will 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.

2. Regulatory Text Change

Additionally, we proposed to revise our regulatory language at § 424.22(a)(1)(v)(D) as to not be prescriptive as to what entity must date and title the face-to-face documentation. The face-to-face documentation must still be signed by the certifying physician, and the content requirements are not changing.

Comment: Commenters were supportive of the proposed regulatory text change.

Response: We thank the commenters for their support.

We are finalizing regulatory text change as proposed. The regulation text in part 424 will be changed to not be prescriptive as to what entity needs to date and title the face-to-face documentation, but will still require the same content and the certifying physician's signature.

E. Therapy Policy Changes

1. Therapy Coverage and Reassessments

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. However, concerns regarding when therapy services are covered if a therapist misses a reassessment visit persist. As a result, in the CY 2013 HH PPS proposed rule issued in the July 13, 2012 **Federal Register** (77 FR 41548), we proposed 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 the late reassessment. In addition, we proposed 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 in a timely manner for the remaining therapy disciplines, therapy services would continue to be covered for those therapy disciplines. We expect minimal changes to claims submissions as a result of these policy changes.

The following is a summary of the comments we received regarding the therapy coverage proposals.

Comment: Commenters were supportive of our proposals to resume coverage of therapy with the visit during which the qualified therapist completed the late reassessment rather than with the visit after the therapist completed late reassessment and 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. In particular, one commenter stated that these proposals will ''remove a barrier to providing necessary, appropriate, and timely home health services'' and ''allows patients to get the care they need without risking a decline in status.''

Response: We agree the reassessment visit should be covered, as therapy was also provided during that visit even though it was not timely. In addition, we also agree that if left unchanged, the current policies have the potential to negatively impact 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.

Comment: Some commenters were confused as to when therapy coverage would resume under the proposals if one or more therapy discipline missed the required reassessment. For example, if a patient receives occupational therapy on visit 11 (with reassessment requirements met) and on visit 14, speech-language pathology services on visit 13 (with reassessment requirements met) and 15, and physical therapy is provided on visit 12 (but did not meet reassessment requirements) and on visit 16 (assessment completed). The commenters questioned whether the CY 2013 HH PPS proposed rule would allow for ongoing coverage of occupational therapy and speech-language pathology and would allow for coverage of physical therapy on visit 16, when the reassessment was completed.

Response: Under the scenario above, the commenters are correct and the proposal would allow for ongoing coverage of occupational therapy and speech-language pathology and would allow for coverage of physical therapy on visit 16, when the reassessment was completed. The physical therapy provided on visit 12 would be non-covered.

We are finalizing the therapy coverage proposals as proposed. The regulation text at § 409.44(c)(2)(i)(E) will be revised 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 the late reassessment. In addition, the regulation text at § 409.44(c)(2)(i)(E) will be revised 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.

2. When Therapy Reassessment Visits Are To Be Conducted

Currently our regulations at § 409.44(c)(2)(i)(C)(2) and § 409.44(c)(2)(i)(D)(2) state that in cases where the patient is receiving more than one type of therapy, the qualified therapist from each discipline must provide all of the therapy, and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur close to the 14th Medicare-covered therapy visit, but no later than the 13th Medicare-covered therapy visit and a qualified therapist from each discipline must provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur close to the 20th Medicare-covered therapy visit, but no later than the 19th Medicare-covered therapy visit. However, because we received numerous inquiries from the home health industry on what CMS considered ''close to,'' we believed that more precise guidance was needed. As a result, we proposed 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 must 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.

The following is a summary of the comments we received regarding the therapy reassessment proposal.

Comment: Several commenters were supportive of the proposal specifying where the patient is receiving more than one type of therapy, qualified therapists must 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.

Response: We thank the commenters for their support. We received numerous questions from the home health industry about what CMS considered ''close to'' the 13th and 19th visit under current policy. We believe that the range proposed, which mirrors the flexibility already in regulation for therapy provided in rural areas, in most cases provides sufficient flexibility for qualified therapists from each discipline to functionally reassess the patient.

Comment: Several commenters stated that often times different therapy modalities will have different frequencies depending on patient need. As such, the proposal specifying ranges in which the 13th and 19th reassessment visits can be conducted when the patient is receiving more than one type of therapy restricts the flexibility in completing assessments that the ''close to'' language provides. In addition, commenters stated that the proposal may result in HHAs providing an extra unnecessary visit or delaying visits to ensure that the agency is in compliance with completing the required assessments during the specified window of time. Commenters provided several schedule examples illustrating instances where therapies provided at varying frequencies would result in having the HHA either provide extra unnecessary therapy visits or delaying therapy visits in order for each discipline to comply with the proposed timeframe for reassessments in multi-therapy cases.

Response: We find compelling the commenters' concerns regarding the feasibility for patients receiving more than one type of therapy of qualified therapists from each of the therapy discipline reassessing the patient within the proposed timeframes when modalities differ significantly in frequency; in those cases we do not expect an HHA to schedule an extra unnecessary visit or delay a visit in order to reassess the patient within the proposed timeframes. Therefore, in instances where patients are receiving more than one type of therapy, and the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra unnecessary visit or delaying a visit, it would still be acceptable and satisfy the reassessment requirement, for the qualified therapist for that discipline to provide the therapy service and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur close to the 14th Medicare-covered therapy visit, but no later than the 13th Medicare-covered therapy visit and for a qualified therapist from each discipline to provide all of the therapy service and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur close to the 20th Medicare-covered therapy visit, but no later than the 19th Medicare-covered therapy visit.

Comment: Several commenters stated that there is a shortage of qualified therapists, especially in rural areas, making compliance with therapy reassessment requirements difficult. Additionally, several commenters stated that too many evaluations were required in a short time period and that the current therapy regulations have added administrative burden, caused scheduling problems, increased clinical and clerical time, require software changes and as a result, there are numerous non-covered visits being provided by HHAs. Moreover, commenters stated that often failure to comply is outside the control of the HHA or therapist, such as unexpected patient illness, hospitalization, or therapist availability.

Response: We thank the commenters for their comments, but these comments are outside the scope of this rule.

However, regarding the administrative burden of these requirements we would like to remind the commenters that the reasons for the therapy reassessments outlined in the CY 2011 HHS PPS final rule (75 FR 70372) were not only to address payment vulnerabilities that have led to high use and sometimes overuse of therapy services, but also to ensure more qualified therapist involvement for beneficiaries receiving high amounts of therapy, which results in better patient outcomes. Regarding factors that are outside of the HHA's control that may result in failure to comply with the reassessment requirements, as we stated above, the regulation text will be amended 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. In addition, changes to the regulation text at § 409.44(c)(2)(i)(E) will be made 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. These two changes should help in reducing the number of non-covered visits that would have otherwise occurred when reassessment visits were missed.

Comment: Several commenters stated that in cases where the patient is not available for therapy services or documented factors preclude a visit, payment would not be denied if the qualified therapist conducts the therapy assessment during the next visit.

Response: As we stated above, the regulation text will be amended 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. In addition, changes to the regulation text at § 409.44(c)(2)(i)(E) will be made 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.

Comment: Several commenters suggested other improvements to streamline the therapy reassessment requirements, including requiring a functional reassessment during the 2nd and 4th weeks of treatment in each episode and during the final week of the episode or 5-day OASIS window, and amending the regulation to require a qualified therapist to perform the assessment and treatment or the qualified therapist perform the assessment and observe the assistant providing the treatment. Several commenters also recommended that a new therapy payment system should be established.

Response: These comments are outside the scope of this rule. We will take the commenters suggestions into consideration for future rulemaking. However, we would like to reiterate that we continue to believe that the requirement for a qualified therapist (instead of an assistant) to perform the needed therapy service at key points in the patient's course of treatment, as well as to assess, measure, and document the effectiveness of the therapy provided, promotes more effective and efficient care.

Comment: One commenter asked that CMS clarify that ''progress'' need not be documented or expected when the patient meets the criteria for maintenance therapy as permitted by the regulations. Specifically, CMS should revise the preamble text in the CY 2013 HH PPS proposed rule (77 FR 41571) that currently reads that ''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.''

Response: To clarify, the regulation text at § 409.44(c)(2)(iv)(B) current states ''clinical records must include documentation using objective measures that the patient continues to progress towards goals. If progress cannot be measured, and continued progress towards goals cannot be expected, therapy services cease to be covered except when (1) Therapy progress regresses or plateaus, and the reasons for lack of progress are documented to include justification that continued therapy treatment will lead to resumption of progress toward goals; or (2) Maintenance therapy as described in § 409.44(c)(2)(iii)(B) or (C) is needed.

We are finalizing our proposal 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 must 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 with the following modification. However, we will also modify the regulation text to state that in instances where patients receive more than one type of therapy, if the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra unnecessary visit or delaying a visit, then it will still be acceptable for the qualified therapist from each discipline to provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 14th Medicare-covered therapy visit, but no later than the 13th Medicare-covered therapy visit. Likewise, a qualified therapist from each discipline must provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 20th Medicare-covered therapy visit, but no later than the 19th Medicare-covered therapy visit.

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 proposed 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.

We received one comment on the proposed technical correction to the G0158 description. The commenter was supportive of the proposed correction and commended CMS on its action to make the code consistent with § 484.4 and national occupational therapy practice standards.

We are finalizing the technical correction to the description for G0158 as proposed.

F. Payment Reform: Home Health Study and Report

Section 3131(d) of the Affordable Care Act requires the Secretary to conduct a study on HHA 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, patients with ''high levels of severity of illness''). In the CY 2013 HH PPS proposed rule, we provided a description of the varied areas for which we have the authority to explore as part of our payment reform activities (77 FR 41572). We continue to conduct analyses, which include evaluating the current HH PPS and developing payment reform options which might minimize vulnerabilities and more accurately align payment with patient resource costs. The Report to Congress regarding the study must be submitted no later than March 1, 2014. We will provide updates regarding our progress in future rulemaking and open door forums.

The following is a summary of the comments we received regarding this study and report.

Comment: Commenters supported the study on access to care for vulnerable populations and stated that they appreciate this undertaking. Commenters also said that they appreciate the specific mention of CMS's demonstration authority of potential revisions to the HH PPS and they saw the study as a solution to many of the problems in the current payment system. One commenter stated that the across the board cuts for nominal case-mix growth as well as the upcoming reductions likely resulting from rebasing will continue to create incentives for providers to avoid vulnerable patients, whose projected cost of care exceeds average-based payments, causing access problems for higher cost patients and threatening the viability of this Medicare program. Another commenter stated that they are seeing access problems for higher cost patients. Commenters stated that they support any effort by CMS to address the needs of vulnerable patient populations and recommended that the study be expedited, if feasible. One commenter stated that they anticipate that the study would include ''an examination of care management models, provider options (including expanded utilization of nurse practitioners), and payment methods that support helping underserved and medically fragile persons remain in their community.'' The commenter stated that they ''look forward to participating in creative solutions that address medical, social and environmental issues that directly impact overall health status and risk for avoidable hospitalization.'' Other commenters urged CMS to consider information from this study when rebasing. Similarly, a commenter stated that CMS should use information from the study, and possible demonstration, to determine a fair payment rate. Commenters also encouraged CMS ''to make fundamental modifications to the payment system to assure that all patients who need home health are served and that the agencies that serve them are not ''financially punished'' for accepting disproportionate numbers of high cost patients.'' Commenters stated that they would like CMS to engage the home health community/industry in developing both regulatory and legislative remedies to other systematic problems in the HH PPS. Another commenter recommended that CMS provide updates to the stakeholder community on the plan and design of the study through different venues, such as a Special Open Door Forum. The commenter believed that physical therapists and home health clinicians should be active participants in the collection and analysis of data for the study.

Response: We will take the commenters' suggestions into consideration when performing the home health study. As described in the CY 2012 proposed rule, we plan to provide updates regarding our progress in future rulemaking and open door forums. We note that we are open to hearing about any instances of access to care issues that vulnerable beneficiaries may face, particularly if they are associated with costs and reimbursement, and potential solutions to access issues.

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

On September 5, 2012 the Department of Health and Human Services published a final 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 54664) that sets a new compliance date for ICD–10–CM and ICD–10–PCS of October 1, 2014. We continue to work with the HH PPS Grouper maintenance contractor to revise the HH PPS Grouper to accommodate ICD–10–CM codes. 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 the summer/fall 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 the payment diagnosis field (M1024 on OASIS–C). 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 on OASIS–C), respectively. Analysis conducted by our HH PPS Grouper maintenance contractor revealed that many HHAs do not comply with these guidelines. Specifically, the analysis demonstrated that HHAs are not limiting the number of diagnoses assigned to the payment diagnosis field and are also reporting resolved conditions in that field. We have reviewed the diagnosis codes identified in the HH PPS Grouper and coding guidelines confirm that the only codes that cannot be reported as a primary or secondary diagnosis code are the fracture codes. As discussed in the CY 2012 HH PPS proposed rule, we proposed two enhancements for the HH PPS Grouper which we believe will encourage compliance with coding guidelines.

First, we proposed to restrict the payment diagnosis field to only permit fracture 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 proposed to pair the fracture codes with appropriate diagnosis codes and only when these pairings appear in the primary payment diagnosis field will the grouper award points.

Second, we proposed a revision to the HH PPS Grouper logic to score Diabetes, Skin 1 or Neuro 1 diagnosis codes when

submitted immediately following a v-code in the primary diagnosis field the same as they are currently scored when a v-code is reported in the primary diagnosis field and the supporting diagnosis code is reported in the payment diagnosis field. As we stated in the proposed rule, these grouper enhancements will enforce appropriate use of our payment diagnosis field based upon our long standing policy and as described in our Attachment D. We believe that in doing so, we will be in a much more favorable position to eventually retire the payment diagnosis field when we move to ICD–10 and there is no longer a need for the payment diagnosis field for the reporting of fracture codes. Finally, we believe these actions will help ensure ICD–9 and ICD–10 coding guidelines are followed; and will assist in the eventual transition of grouping the diagnoses on the claim, versus OASIS, in determining the appropriate HIPPS code for payment.

The following is a summary of the comments we received regarding the ICD–10 Transition Plan and Grouper Enhancements.

Comment: Several commenters supported our plans for the ICD–10–CM transition and look forward to further updates through the final rule and provider outreach sessions. Although some commenters supported our plans to retire the payment diagnosis field, other commenters noted that the OASIS payment field was introduced as a payment vehicle for diagnoses that could no longer be reported in the primary or secondary positions because of HIPAA requirements. Many commenters also stated that Attachment D was designed to permit the submission of resolved conditions in the payment diagnosis field and that a majority of the conditions reported in the payment diagnosis field represent resolved conditions. Many commenters expressed concern that the proposed policy to restrict the payment diagnosis field needed additional clarification and specificity regarding the reporting of the v-code and the limited use of the payment diagnosis field since Attachment D is not sufficient. Several commenters also urged us to update Attachment D to reflect changes in the OASIS and ICD–9–CM coding guidance.

Response: We appreciate that some commenters recognize the need for compliance with ICD–9–CM coding guidelines and recognize that there is a need to update Attachment D and the HH PPS Grouper specifications to reflect the restrictions for the payment diagnosis field. We conducted a review of Attachment D to determine whether further clarification or updates are necessary and conclude that the guidance issued did not fully communicate that the reporting of resolved conditions in the payment diagnosis field should be limited. However, we disagree that the payment diagnosis field was designed to permit ''any'' resolved condition to be reported. In CY 2009, 85 percent of OASIS records did not contain any diagnosis codes in the payment diagnosis field or contained only diagnoses codes that had not been found to be associated with additional resources use and as such as are not included in our grouper nor impacted by this policy. We analyzed the 15 percent of OASIS records that included grouper diagnosis codes in the payment diagnosis field and found that 25 percent of those OASIS records represent fracture conditions which can continue to be reported and scored. Thirty-six percent represent persistent conditions, such as diabetic cataract, in which the underlying condition (diabetes) could be reported as a primary or secondary diagnosis and thus are not impacted by this policy. Thirty-nine percent represent conditions that can be reported in the primary or secondary diagnosis fields if the diagnosis is active rather than resolved and is appropriate for care in the home health setting.

Based on our review and the commenters' recommendations, we agree that Attachment D should be updated to reflect the most current version of OASIS and any changes and clarifications in coding guidance.

Our analysis found that if HHAs were to ensure compliance with coding guidelines, there would not be a need to report a resolved condition with the exception of fractures. Several commenters provided a few examples where they believe the proposed policy would result in a decrease in case mix points. One such example is of a low therapy patient admitted to home health for post-operative care following surgical resolution of an intestinal obstruction would also have a surgical wound that receives a lower score. Although this example and others could result in a lower score, the diagnosis codes being reported in the payment diagnosis field suggests that these are extremely rare types of episodes and the impact is negligible. We found that more than 99.6 percent of assessments would continue to receive the same case-mix weight when the payment diagnosis field is restricted to fracture codes only, resulting in a 0.04 percent decrease in payments to HHAs.

Oftentimes, the HHA selected and reported a condition within the same diagnosis group as the condition reported in the payment diagnosis field or should have selected another diagnosis within the codes included in the grouper diagnosis group to report as a resolving condition in primary or secondary diagnosis fields. In either case, restricting the awarding of points to fracture conditions will ensure that HHAs avoid selection of diagnosis codes that are not in compliance with coding guidelines.

Comment: Several commenters noted concerns that CMS is proposing changes for the payment diagnosis field when there is not a problem. One commenter presented data reported in the Medicare and Medicaid Statistical Supplement to demonstrate that there has been a decrease in v-code reporting from 2000 through 2009.

Response: Although, there has been a decrease in the number of OASIS records submitted that utilize the payment diagnosis field over the last 4 years the volume is still at odds with guidance to code sparingly. We must ensure that the HHAs report diagnosis codes that comply with ICD–9–CM coding guidelines. Thus, the restriction proposed for the payment diagnosis field reporting ensures greater compliance with coding guidelines. Furthermore, the restriction supports our future plans to use diagnosis information from the claims, rather than OASIS, to determine the appropriate HIPPS code for payment.

Comment: Many commenters provided several examples where they would be impacted, if this policy is implemented, such as osteoarthritis related to hip replacement, cholelithiasis due to a cholecystectomy, breast neoplasm following a mastectomy, amputation due to a non-pressure ulcer and meningitis. Many commenters stated that when the payment diagnosis field was added to the OASIS, it was an assurance to the industry to accommodate the reporting of v-codes and receive points for resolved conditions such as those resolved by surgery.

Response: The home health payment is based on resources required to care for the patient in their current condition. For example, if the patient has a resolved orthopedic condition (osteoarthritis of the hip resolved following hip replacement) the episode will receive points based on any active comorbid diagnoses plus clinical status (such as surgical wound), functional impairments (such as problems with ambulation or transferring), and therapy needs. Given the fact that some HHAs may have incorrectly interpreted the guidance in Attachment D, and were

reporting resolved conditions, such as those resolved by surgery, which may have resulted in the awarding of points; this final rule clarifies that with the exception of fracture codes, resolved conditions are not appropriate for coding in the home health setting, and will not be awarded points when reported.

Comment: Many commenters expressed concern that we did not provide a cost analysis prior to proposing this policy because they believe that the restricted use of the payment diagnosis field to fracture codes would result in a large reduction in payments to HHAs such as two hundred dollars for certain episodes. We also received comments that express concern that the policy is not budget neutral or assumed that the proposed policy would be budget neutral. One commenter raised concerns that the payment diagnosis field changes may have an impact on agency risk adjustment of quality measures that are publicly reported. The commenters expressed concern that by not permitting the reporting of resolved conditions we would be preventing HHAs from reporting important information that further describes the patient. In addition, a few commenters noted that changing our HH PPS reimbursement when rebasing is being studied is not reasonable.

Response: As we indicated in response to comments received on resolved conditions, if the resolved condition is still impacting the patient, these impacts are captured by the clinical and functional data reported in the OASIS rather than the diagnosis. As stated above, we found that more than 99.6 percent of assessments would continue to receive the same case-mix weight when the payment diagnosis field is restricted to fracture codes only, resulting in a 0.04 percent decrease in payments to HHAs. These payments should not have been made because they do not reflect resources to care for the patient, nor do these coding practices comply with ICD–9 coding guidelines, and thus reflect inappropriate coding practices. Our primary purpose is to ensure compliance with ICD–9–CM coding guidelines. Implementing these changes in a budget neutral manner is not applicable in this instance because HHAs should not receive reimbursement for a resolved condition with the exception of fracture conditions.

Abt Associates analyzed data from a 20 percent sample of all home health episodes from 2009, or 1.2 million episodes. The total number of episodes with an acceptable v-code paired with any ICD–9–CM code in the case mix grouper was approximately 174,000 episodes. These data were drawn from the Home Health Datalink, a file that links the OASIS assessments to the corresponding home health claim. Abt Associates conducted three separate sets of analyses. The first analysis assumes that only fracture codes are recognized as payment diagnoses and did not reflect any accompanying change in agency coding behavior. This analysis showed that 99.3 percent of assessments would continue to receive the same case-mix weight. The second analysis assumes that agencies code for fracture and also assumes that, for many resolved conditions, agencies will be able to code underlying persistent conditions as primary or secondary diagnoses (for example, coding diabetes after a diabetic cataract has been removed). This analysis showed that 99.6 percent of assessments would continue to receive the same case-mix weight. Finally, the third analysis makes the first two analytical assumptions above and also assumes that, for some additional conditions currently reported in the payment diagnosis field, agencies will be able to code alternate codes that scores points for the same diagnosis group. This analysis also showed that 99.6 percent of assessments would continue to receive the same case-mix weight. Although commenters asserted that there would be a significant impact, the three sets of analyses found that HH episodes would essentially continue to be scored the same once this policy is implemented as revised.

The risk adjustment models for the quality measures that are publicly reported use all the diagnoses that appear on the OASIS (in the primary, secondary, payment diagnosis field as well as the inpatient diagnosis). Although we do not necessarily agree that by preventing resolved conditions related to the plan of care to be reported we are losing significant information that describes the patient, we are willing to modify our policy in the short term to allow these conditions to be reported in the payment diagnosis field but will restrict the awarding of points only to fracture conditions. We believe that modifying our policy to permit this type of reporting in the payment diagnosis field will address the concern expressed by commenters that wanted to be able to report additional clinical information and public health information about the patient while still allowing the agency to move forward with our plans to group the claim, versus OASIS, to determine the appropriate HIPPS code for payment.

Comment: We received several comments in support of the proposed logic changes specific to the reporting requirements for secondary conditions found in Neuro, Skin 1, or Ortho 1. Several commenters noted that once ICD–10–CM is implemented, the payment diagnosis field will no longer be needed for the reporting of fracture diagnosis codes. However, they advise us that our proposal to restrict the use of the payment diagnosis field to only fracture diagnosis codes if paired with an appropriate v-code in the primary and payment diagnosis fields is not representative of all the sequencing requirements for fracture aftercare. Specifically, some encounters are reported as a secondary diagnosis because they may not be the primary reason for admission. Therefore, we should include v-codes reported as a secondary condition when paired with a fracture code in the payment diagnosis field. A few commenters would have liked to see a draft listing of the v-code pairings in our proposed rule.

Response: We appreciate the supportive comments to eventually eliminate the payment diagnosis field once ICD–10 is fully implemented and the recommendation to review the sequencing requirements. We agree that restricting the payment diagnosis field to only fracture diagnosis codes reported as primary is not representative of the all the sequencing requirements for fracture aftercare. We will revise the HH PPS grouper logic to award points when fracture codes in the payment diagnosis field are paired with v-codes in either the primary or secondary diagnosis fields. As requested by a few commenters, we have provided a list of valid fracture conditions within our grouper paired with appropriate v-codes (See Table 25).

Comment: Several commenters recommend that we rescind or delay the proposed change to restrict the payment diagnosis field to fracture codes only.

Response: We appreciate the feedback. However, we believe that we have sufficiently described and explained our rationale for restricting the awarding of points for fracture codes only. As we stated above, this proposal will allow us to eventually eliminate the payment diagnosis field once ICD–10 is fully implemented and ensure that agencies are in full compliance, where possible, with coding guidelines before ICD–10 is implemented.

Comment: Several commenters noted that logic within Home Assessment Validation and Entry System (HAVEN) has contributed to the confusion

surrounding v-code reporting by suggesting that the software would not group the record (that is, determine the appropriate home health resource group) when a v-code was reported in the primary position. The commenters noted that vendors have adopted similar logic within their own software to require v-code reporting even when the ICD–9–CM v-code does not require a diagnosis code to explain the reason for aftercare.

Response: We appreciate the feedback and will consider whether any changes should be made to edits within HAVEN.

Comment: We also received comments outside the scope of the proposed policy. Specifically, a commenter suggested that we should Return to Provider (RTP) claims when edits do not permit the proper adjudication versus implementing this policy. In addition, other commenters suggested that CMS should acknowledge the use of certified coders in homecare by permitting them to correct inaccurate coding.

Response: These comments are outside the scope of this rule, and therefore, we are not addressing these issues in this rule.

We are implementing the Grouper enhancements as proposed with two modifications. We will be modifying our policy for the payment diagnosis field to reflect that when v-codes are reported as a primary or secondary diagnosis and paired with a fracture code in our pairing listing, the grouper will award points. We will also be modifying our policy for the payment diagnosis field to permit the reporting of resolved conditions related to the plan of care that may be significant in describing the patient but will restrict the awarding of points to fracture conditions.

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Table 25: HH PPS Grouper, Fracture Conditions and Appropriate V-Codes, CY 2013

V-Code	Description	ICD Pair	Description
V54.10	Aftrcre traum fx arm NOS	818.0	Fx arm mult/NOS-closed
		818.1	Fx arm mult/NOS-open
V54.11	Aftrcare traum fx up arm	812.00	Fx up end humerus NOS-cl
		812.01	Fx surg nck humerus-clos
		812.02	Fx anatom nck humerus-cl
		812.03	Fx gr tuberos humerus-cl
		812.09	Fx upper humerus NEC-cl
		812.10	Fx upper humerus NOS-opn
		812.11	Fx surg neck humerus-opn
		812.12	Fx anat neck humerus-opn
		812.13	Fx gr tuberos humer-open
		812.19	Fx upper humerus NEC-opn
		812.20	Fx humerus NOS-closed
		812.21	Fx humerus shaft-closed
		812.30	Fx humerus NOS-open
		812.31	Fx humerus shaft-open
		812.40	Fx lower humerus NOS-cl
		812.41	Suprcondyl fx humerus-cl
		812.42	Fx humer, lat condyl-cl
		812.43	Fx humer, med condyl-cl
		812.44	Fx humer, condyl NOS-cl
		812.49	Fx lower humerus NEC-cl
		812.50	Fx lower humer NOS-open
		812.51	Supracondyl fx humer-opn
		812.52	Fx humer, lat condyl-opn
		812.53	Fx humer, med condyl-opn
		812.54	Fx humer, condyl NOS-opn
		812.59	Fx lower humer NEC-open
V54.12	Aftrcre traum fx low arm	813.00	Fx upper forearm NOS-cl
		813.01	Fx olecran proc ulna-cl
		813.02	Fx coronoid proc ulna-cl
		813.03	Monteggia's fx-closed
		813.04	Fx upper ulna NEC/NOS-cl
		813.05	Fx radius head-closed
		813.06	Fx radius neck-closed
		813.07	Fx up radius NEC/NOS-cl
		813.08	Fx up radius w ulna-clos
		813.10	Fx upper forearm NOS-opn

V-Code	Description	ICD Pair	Description
		813.11	Fx olecran proc ulna-opn
		813.12	Fx coronoid pro ulna-opn
		813.13	Monteggia's fx-open
		813.14	Fx up ulna NEC/NOS-open
		813.15	Fx radius head-open
		813.16	Fx radius neck-open
		813.17	Fx up radius NEC/NOS-opn
		813.18	Fx up radius w ulna-open
		813.20	Fx shaft forearm NOS-cl
		813.21	Fx radius shaft-closed
		813.22	Fx ulna shaft-closed
		813.23	Fx shaft rad w ulna-clos
		813.30	Fx shaft forearm NOS-opn
		813.31	Fx radius shaft-open
		813.32	Fx ulna shaft-open
		813.33	Fx shaft rad w ulna-open
		813.40	Fx lower forearm NOS-cl
		813.41	Colles' fracture-closed
		813.42	Fx distal radius NEC-cl
		813.43	Fx distal ulna-closed
		813.44	Fx low radius w ulna-cl
		813.45	Torus fx radius-closed
		813.46	Torus fracture of ulna (alone)
		813.47	Torus fracture of radius and ulna
		813.50	Fx lower forearm NOS-opn
		813.51	Colles' fracture-open
		813.52	Fx distal radius NEC-opn
		813.53	Fx distal ulna-open
		813.54	Fx low radius w ulna-opn
		813.80	Fx forearm NOS-closed
		813.81	Fx radius NOS-closed
		813.82	Fracture ulna NOS-closed
		813.83	Fx radius w ulna NOS-cl
		813.90	Fx forearm NOS-open
		813.91	Fracture radius NOS-open
		813.92	Fracture ulna NOS-open
		813.93	Fx radius w ulna NOS-opn
V54.13	Aftrcre traumatic fx hip	820.00	Fx femur intrcaps NOS-cl
		820.01	Fx up femur epiphy-clos
		820.02	Fx femur, midcervic-clos

V-Code	Description	ICD Pair	Description
		820.03	Fx base femoral nck-clos
		820.09	Fx femur intrcaps NEC-cl
		820.10	Fx femur intrcap NOS-opn
		820.11	Fx up femur epiphy-open
		820.12	Fx femur, midcervic-open
		820.13	Fx base femoral nck-open
		820.19	Fx femur intrcap NEC-opn
		820.20	Trochanteric fx NOS-clos
		820.21	Intertrochanteric fx-cl
		820.22	Subtrochanteric fx-close
		820.30	Trochanteric fx NOS-open
		820.31	Intertrochanteric fx-opn
		820.32	Subtrochanteric fx-open
		820.8	Fx neck of femur NOS-cl
		820.9	Fx neck of femur NOS-opn
V54.14	Aftrcre traum fx leg NOS	827.0	Fx lower limb NEC-closed
		827.1	Fx lower limb NEC-open
V54.15	Aftrcare traum fx up leg	821.00	Fx femur NOS-closed
		821.01	Fx femur shaft-closed
		821.10	Fx femur NOS-open
		821.11	Fx femur shaft-open
		821.20	Fx low end femur NOS-cl
		821.21	Fx femoral condyle-close
		821.22	Fx low femur epiphy-clos
		821.23	Supracondyl fx femur-cl
		821.29	Fx low end femur NEC-cl
		821.30	Fx low end femur NOS-opn
		821.31	Fx femoral condyle-open
		821.32	Fx low femur epiphy-open
		821.33	Supracondyl fx femur-opn
		821.39	Fx low end femur NEC-opn
V54.16	Aftrcre traum fx low leg	822.0	Fracture patella-closed
		822.1	Fracture patella-open
		823.00	Fx upper end tibia-close
		823.01	Fx upper end fibula-clos
		823.02	Fx up tibia w fibula-cl
		823.10	Fx upper end tibia-open
		823.11	Fx upper end fibula-open
		823.12	Fx up tibia w fibula-opn
		823.20	Fx shaft tibia-closed

V-Code	Description	ICD Pair	Description
		823.21	Fx shaft fibula-closed
		823.22	Fx shaft fib w tib-clos
		823.30	Fx tibia shaft-open
		823.31	Fx fibula shaft-open
		823.32	Fx shaft tibia w fib-opn
		823.40	Torus fracture of tibia
		823.41	Torus fracture of fibula
		823.42	Torus fx tibia/fibula
		823.80	Fx tibia NOS-closed
		823.81	Fx fibula NOS-closed
		823.82	Fx tibia w fibula NOS-cl
		823.90	Fx tibia NOS-open
		823.91	Fx fibula NOS-open
		823.92	Fx tibia w fib NOS-open
V54.17	Aftrcre traum fx vertebr	805.00	Fx cervical vert NOS-cl
		805.01	Fx c1 vertebra-closed
		805.02	Fx c2 vertebra-closed
		805.03	Fx c3 vertebra-closed
		805.04	Fx c4 vertebra-closed
		805.05	Fx c5 vertebra-closed
		805.06	Fx c6 vertebra-closed
		805.07	Fx c7 vertebra-closed
		805.08	Fx mult cervical vert-cl
		805.10	Fx cervical vert NOS-opn
		805.11	Fx c1 vertebra-open
		805.12	Fx c2 vertebra-open
		805.13	Fx c3 vertebra-open
		805.14	Fx c4 vertebra-open
		805.15	Fx c5 vertebra-open
		805.16	Fx c6 vertebra-open
		805.17	Fx c7 vertebra-open
		805.18	Fx mlt cervical vert-opn
		805.2	Fx dorsal vertebra-close
		805.3	Fx dorsal vertebra-open
		805.4	Fx lumbar vertebra-close
		805.5	Fx lumbar vertebra-open
		805.6	Fx sacrum/coccyx-closed
		805.7	Fx sacrum/coccyx-open
		805.8	Vertebral fx NOS-closed
		805.9	Vertebral fx NOS-open

V-Code	Description	ICD Pair	Description
		806.00	C1-c4 fx-cl/cord inj NOS
		806.01	C1-c4 fx-cl/com cord les
		806.02	C1-c4 fx-cl/ant cord syn
		806.03	C1-c4 fx-cl/cen cord syn
		806.04	C1-c4 fx-cl/cord inj NEC
		806.05	C5-c7 fx-cl/cord inj NOS
		806.06	C5-c7 fx-cl/com cord les
		806.07	C5-c7 fx-cl/ant cord syn
		806.08	C5-c7 fx-cl/cen cord syn
		806.09	C5-c7 fx-cl/cord inj NEC
		806.10	C1-c4 fx-op/cord inj NOS
		806.11	C1-c4 fx-op/com cord les
		806.12	C1-c4 fx-op/ant cord syn
		806.13	C1-c4 fx-op/cen cord syn
		806.14	C1-c4 fx-op/cord inj NEC
		806.15	C5-c7 fx-op/cord inj NOS
		806.16	C5-c7 fx-op/com cord les
		806.17	C5-c7 fx-op/ant cord syn
		806.18	C5-c7 fx-op/cen cord syn
		806.19	C5-c7 fx-op/cord inj NEC
		806.20	T1-t6 fx-cl/cord inj NOS
		806.21	T1-t6 fx-cl/com cord les
		806.22	T1-t6 fx-cl/ant cord syn
		806.23	T1-t6 fx-cl/cen cord syn
		806.24	T1-t6 fx-cl/cord inj NEC
		806.25	T7-t12 fx-cl/crd inj NOS
		806.26	T7-t12 fx-cl/com crd les
		806.27	T7-t12 fx-cl/ant crd syn
		806.28	T7-t12 fx-cl/cen crd syn
		806.29	T7-t12 fx-cl/crd inj NEC
		806.30	T1-t6 fx-op/cord inj NOS
		806.31	T1-t6 fx-op/com cord les
		806.32	T1-t6 fx-op/ant cord syn
		806.33	T1-t6 fx-op/cen cord syn
		806.34	T1-t6 fx-op/cord inj NEC
		806.35	T7-t12 fx-op/crd inj NOS
		806.36	T7-t12 fx-op/com crd les
		806.37	T7-t12 fx-op/ant crd syn
		806.38	T7-t12 fx-op/cen crd syn
		806.39	T7-t12 fx-op/crd inj NEC

V-Code	Description	ICD Pair	Description
		806.4	Cl lumbar fx w cord inj
		806.5	Opn lumbar fx w cord inj
		806.60	Fx sacrum-cl/crd inj NOS
		806.61	Fx sacr-cl/cauda equ les
		806.62	Fx sacr-cl/cauda inj NEC
		806.69	Fx sacrum-cl/crd inj NEC
		806.70	Fx sacrum-op/crd inj NOS
		806.71	Fx sacr-op/cauda equ les
		806.72	Fx sacr-op/cauda inj NEC
		806.79	Fx sacrum-op/crd inj NEC
		806.8	Vert fx NOS-cl w crd inj
		806.9	Vert fx NOS-op w crd inj
V54.19	Aftrce traum fx bone NEC	800.00	Closed skull vault fx
		800.01	Cl skull vlt fx w/o coma
		800.02	Cl skull vlt fx-brf coma
		800.03	Cl skull vlt fx-mod coma
		800.04	Cl skl vlt fx-proln coma
		800.05	Cl skul vlt fx-deep coma
		800.06	Cl skull vlt fx-coma NOS
		800.09	Cl skl vlt fx-concus NOS
		800.10	Cl skl vlt fx/cerebr lac
		800.11	Cl skull vlt fx w/o coma
		800.12	Cl skull vlt fx-brf coma
		800.13	Cl skull vlt fx-mod coma
		800.14	Cl skl vlt fx-proln coma
		800.15	Cl skul vlt fx-deep coma
		800.16	Cl skull vlt fx-coma NOS
		800.19	Cl skl vlt fx-concus NOS
		800.20	Cl skl vlt fx/mening hem
		800.21	Cl skull vlt fx w/o coma
		800.22	Cl skull vlt fx-brf coma
		800.23	Cl skull vlt fx-mod coma
		800.24	Cl skl vlt fx-proln coma
		800.25	Cl skul vlt fx-deep coma
		800.26	Cl skull vlt fx-coma NOS
		800.29	Cl skl vlt fx-concus NOS
		800.30	Cl skull vlt fx/hem NEC
		800.31	Cl skull vlt fx w/o coma
		800.32	Cl skull vlt fx-brf coma
		800.33	Cl skull vlt fx-mod coma

V-Code	Description	ICD Pair	Description
		800.34	Cl skl vlt fx-proln coma
		800.35	Cl skul vlt fx-deep coma
		800.36	Cl skull vlt fx-coma NOS
		800.39	Cl skl vlt fx-concus NOS
		800.40	Cl skl vlt fx/br inj NEC
		800.41	Cl skull vlt fx w/o coma
		800.42	Cl skull vlt fx-brf coma
		800.43	Cl skull vlt fx-mod coma
		800.44	Cl skl vlt fx-proln coma
		800.45	Cl skul vlt fx-deep coma
		800.46	Cl skull vlt fx-coma NOS
		800.49	Cl skl vlt fx-concus NOS
		800.50	Opn skull vault fracture
		800.51	Opn skul vlt fx w/o coma
		800.52	Opn skul vlt fx-brf coma
		800.53	Opn skul vlt fx-mod coma
		800.54	Opn skl vlt fx-proln com
		800.55	Opn skl vlt fx-deep coma
		800.56	Opn skul vlt fx-coma NOS
		800.59	Op skl vlt fx-concus NOS
		800.60	Opn skl vlt fx/cereb lac
		800.61	Opn skul vlt fx w/o coma
		800.62	Opn skul vlt fx-brf coma
		800.63	Opn skul vlt fx-mod coma
		800.64	Opn skl vlt fx-proln com
		800.65	Opn skl vlt fx-deep coma
		800.66	Opn skul vlt fx-coma NOS
		800.69	Op skl vlt fx-concus NOS
		800.70	Opn skl vlt fx/menin hem
		800.71	Opn skul vlt fx w/o coma
		800.72	Opn skul vlt fx-brf coma
		800.73	Opn skul vlt fx-mod coma
		800.74	Opn skl vlt fx-proln com
		800.75	Opn skl vlt fx-deep coma
		800.76	Opn skul vlt fx-coma NOS
		800.79	Op skl vlt fx-concus NOS
		800.80	Opn skull vlt fx/hem NEC
		800.81	Opn skul vlt fx w/o coma
		800.82	Opn skul vlt fx-brf coma
		800.83	Opn skul vlt fx-mod coma

V-Code	Description	ICD Pair	Description
		800.84	Opn skl vlt fx-proln com
		800.85	Opn skl vlt fx-deep coma
		800.86	Opn skul vlt fx-coma NOS
		800.89	Op skl vlt fx-concus NOS
		800.90	Op skl vlt fx/br inj NEC
		800.91	Opn skul vlt fx w/o coma
		800.92	Opn skul vlt fx-brf coma
		800.93	Opn skul vlt fx-mod coma
		800.94	Opn skl vlt fx-proln com
		800.95	Op skul vlt fx-deep coma
		800.96	Opn skul vlt fx-coma NOS
		800.99	Op skl vlt fx-concus NOS
		801.00	Clos skull base fracture
		801.01	Cl skul base fx w/o coma
		801.02	Cl skul base fx-brf coma
		801.03	Cl skul base fx-mod coma
		801.04	Cl skl base fx-prol coma
		801.05	Cl skl base fx-deep coma
		801.06	Cl skul base fx-coma NOS
		801.09	Cl skull base fx-concuss
		801.10	Cl skl base fx/cereb lac
		801.11	Cl skul base fx w/o coma
		801.12	Cl skul base fx-brf coma
		801.13	Cl skul base fx-mod coma
		801.14	Cl skl base fx-prol coma
		801.15	Cl skl base fx-deep coma
		801.16	Cl skul base fx-coma NOS
		801.19	Cl skull base fx-concuss
		801.20	Cl skl base fx/menin hem
		801.21	Cl skul base fx w/o coma
		801.22	Cl skul base fx/brf coma
		801.23	Cl skul base fx-mod coma
		801.24	Cl skl base fx-prol coma
		801.25	Cl skl base fx-deep coma
		801.26	Cl skul base fx-coma NOS
		801.29	Cl skull base fx-concuss
		801.30	Cl skull base fx/hem NEC
		801.31	Cl skul base fx w/o coma
		801.32	Cl skul base fx-brf coma
		801.33	Cl skul base fx-mod coma

V-Code	Description	ICD Pair	Description
		801.34	Cl skl base fx-prol coma
		801.35	Cl skl base fx-deep coma
		801.36	Cl skul base fx-coma NOS
		801.39	Cl skull base fx-concuss
		801.40	Cl sk base fx/br inj NEC
		801.41	Cl skul base fx w/o coma
		801.42	Cl skul base fx-brf coma
		801.43	Cl skul base fx-mod coma
		801.44	Cl skl base fx-prol coma
		801.45	Cl skl base fx-deep coma
		801.46	Cl skul base fx-coma NOS
		801.49	Cl skull base fx-concuss
		801.50	Open skull base fracture
		801.51	Opn skl base fx w/o coma
		801.52	Opn skl base fx-brf coma
		801.53	Opn skl base fx-mod coma
		801.54	Op skl base fx-prol coma
		801.55	Op skl base fx-deep coma
		801.56	Opn skl base fx-coma NOS
		801.59	Opn skul base fx-concuss
		801.60	Op skl base fx/cereb lac
		801.61	Opn skl base fx w/o coma
		801.62	Opn skl base fx-brf coma
		801.63	Opn skl base fx-mod coma
		801.64	Op skl base fx-prol coma
		801.65	Op skl base fx-deep coma
		801.66	Opn skl base fx-coma NOS
		801.69	Opn skul base fx-concuss
		801.70	Op skl base fx/menin hem
		801.71	Opn skl base fx w/o coma
		801.72	Opn skl base fx-brf coma
		801.73	Opn skl base fx-mod coma
		801.74	Op skl base fx-prol coma
		801.75	Op skl base fx-deep coma
		801.76	Opn skl base fx-coma NOS
		801.79	Opn skul base fx-concuss
		801.80	Opn skul base fx/hem NEC
		801.81	Opn skl base fx w/o coma
		801.82	Opn skl base fx-brf coma
		801.83	Opn skl base fx-mod coma

V-Code	Description	ICD Pair	Description
		801.84	Op skl base fx-prol coma
		801.85	Op skl base fx-deep coma
		801.86	Opn skl base fx-coma NOS
		801.89	Opn skul base fx-concuss
		801.90	Op sk base fx/br inj NEC
		801.91	Op skul base fx w/o coma
		801.92	Opn skl base fx-brf coma
		801.93	Opn skl base fx-mod coma
		801.94	Op skl base fx-prol coma
		801.95	Op skl base fx-deep coma
		801.96	Opn skl base fx-coma NOS
		801.99	Opn skul base fx-concuss
		802.0	Nasal bone fx-closed
		802.1	Nasal bone fx-open
		802.20	Mandible fx NOS-closed
		802.21	Fx condyl proc mandib-cl
		802.22	Subcondylar fx mandib-cl
		802.23	Fx coron proc mandib-cl
		802.24	Fx ramus NOS-closed
		802.25	Fx angle of jaw-closed
		802.26	Fx symphy mandib body-cl
		802.27	Fx alveolar bord mand-cl
		802.28	Fx mandible body NEC-cl
		802.29	Mult fx mandible-closed
		802.30	Mandible fx NOS-open
		802.31	Fx condyl proc mand-open
		802.32	Subcondyl fx mandib-open
		802.33	Fx coron proc mandib-opn
		802.34	Fx ramus NOS-open
		802.35	Fx angle of jaw-open
		802.36	Fx symphy mandib bdy-opn
		802.37	Fx alv bord mand bdy-opn
		802.38	Fx mandible body NEC-opn
		802.39	Mult fx mandible-open
		802.4	Fx malar/maxillary-close
		802.5	Fx malar/maxillary-open
		802.6	Fx orbital floor-closed
		802.7	Fx orbital floor-open
		802.8	Fx facial bone NEC-close
		802.9	Fx facial bone NEC-open

V-Code	Description	ICD Pair	Description
		803.00	Close skull fracture NEC
		803.01	Cl skull fx NEC w/o coma
		803.02	Cl skull fx NEC-brf coma
		803.03	Cl skull fx NEC-mod coma
		803.04	Cl skl fx NEC-proln coma
		803.05	Cl skul fx NEC-deep coma
		803.06	Cl skull fx NEC-coma NOS
		803.09	Cl skull fx NEC-concuss
		803.10	Cl skl fx NEC/cerebr lac
		803.11	Cl skull fx NEC w/o coma
		803.12	Cl skull fx NEC-brf coma
		803.13	Cl skull fx NEC-mod coma
		803.14	Cl skl fx NEC-proln coma
		803.15	Cl skul fx NEC-deep coma
		803.16	Cl skull fx NEC-coma NOS
		803.19	Cl skull fx NEC-concuss
		803.20	Cl skl fx NEC/mening hem
		803.21	Cl skull fx NEC w/o coma
		803.22	Cl skull fx NEC-brf coma
		803.23	Cl skull fx NEC-mod coma
		803.24	Cl skl fx NEC-proln coma
		803.25	Cl skul fx NEC-deep coma
		803.26	Cl skull fx NEC-coma NOS
		803.29	Cl skull fx NEC-concuss
		803.30	Cl skull fx NEC/hem NEC
		803.31	Cl skull fx NEC w/o coma
		803.32	Cl skull fx NEC-brf coma
		803.33	Cl skull fx NEC-mod coma
		803.34	Cl skl fx NEC-proln coma
		803.35	Cl skul fx NEC-deep coma
		803.36	Cl skull fx NEC-coma NOS
		803.39	Cl skull fx NEC-concuss
		803.40	Cl skl fx NEC/br inj NEC
		803.41	Cl skull fx NEC w/o coma
		803.42	Cl skull fx NEC-brf coma
		803.43	Cl skull fx NEC-mod coma
		803.44	Cl skl fx NEC-proln coma
		803.45	Cl skul fx NEC-deep coma
		803.46	Cl skull fx NEC-coma NOS
		803.49	Cl skull fx NEC-concuss

V-Code	Description	ICD Pair	Description
		803.50	Open skull fracture NEC
		803.51	Opn skul fx NEC w/o coma
		803.52	Opn skul fx NEC-brf coma
		803.53	Opn skul fx NEC-mod coma
		803.54	Opn skl fx NEC-prol coma
		803.55	Opn skl fx NEC-deep coma
		803.56	Opn skul fx NEC-coma NOS
		803.59	Opn skull fx NEC-concuss
		803.60	Opn skl fx NEC/cereb lac
		803.61	Opn skul fx NEC w/o coma
		803.62	Opn skul fx NEC-brf coma
		803.63	Opn skul fx NEC-mod coma
		803.64	Opn skl fx NEC-proln com
		803.65	Opn skl fx NEC-deep coma
		803.66	Opn skul fx NEC-coma NOS
		803.69	Opn skull fx NEC-concuss
		803.70	Opn skl fx NEC/menin hem
		803.71	Opn skul fx NEC w/o coma
		803.72	Opn skul fx NEC-brf coma
		803.73	Opn skul fx NEC-mod coma
		803.74	Opn skl fx NEC-prol coma
		803.75	Opn skl fx NEC-deep coma
		803.76	Opn skul fx NEC-coma NOS
		803.79	Opn skull fx NEC-concuss
		803.80	Opn skull fx NEC/hem NEC
		803.81	Opn skul fx NEC w/o coma
		803.82	Opn skul fx NEC-brf coma
		803.83	Opn skul fx NEC-mod coma
		803.84	Opn skl fx NEC-prol coma
		803.85	Opn skl fx NEC-deep coma
		803.86	Opn skul fx NEC-coma NOS
		803.89	Opn skull fx NEC-concuss
		803.90	Op skl fx NEC/br inj NEC
		803.91	Opn skul fx NEC w/o coma
		803.92	Opn skul fx NEC-brf coma
		803.93	Opn skul fx NEC-mod coma
		803.94	Opn skl fx NEC-prol coma
		803.95	Opn skl fx NEC-deep coma
		803.96	Opn skul fx NEC-coma NOS
		803.99	Opn skull fx NEC-concuss

V-Code	Description	ICD Pair	Description
		804.00	Cl skul fx w oth bone fx
		804.01	Cl skl w oth fx w/o coma
		804.02	Cl skl w oth fx-brf coma
		804.03	Cl skl w oth fx-mod coma
		804.04	Cl skl/oth fx-proln coma
		804.05	Cl skul/oth fx-deep coma
		804.06	Cl skl w oth fx-coma NOS
		804.09	Cl skul w oth fx-concuss
		804.10	Cl sk w oth fx/cereb lac
		804.11	Cl skl w oth fx w/o coma
		804.12	Cl skl w oth fx-brf coma
		804.13	Cl skl w oth fx-mod coma
		804.14	Cl skl/oth fx-proln coma
		804.15	Cl skul/oth fx-deep coma
		804.16	Cl skl w oth fx-coma NOS
		804.19	Cl skul w oth fx-concuss
		804.20	Cl skl/oth fx/mening hem
		804.21	Cl skl w oth fx w/o coma
		804.22	Cl skl w oth fx-brf coma
		804.23	Cl skl w oth fx-mod coma
		804.24	Cl skl/oth fx-proln coma
		804.25	Cl skul/oth fx-deep coma
		804.26	Cl skl w oth fx-coma NOS
		804.29	Cl skul w oth fx-concuss
		804.30	Cl skul w oth fx/hem NEC
		804.31	Cl skl w oth fx w/o coma
		804.32	Cl skl w oth fx-brf coma
		804.33	Cl skl w oth fx-mod coma
		804.34	Cl skl/oth fx-proln coma
		804.35	Cl skul/oth fx-deep coma
		804.36	Cl skl w oth fx-coma NOS
		804.39	Cl skul w oth fx-concuss
		804.40	Cl skl/oth fx/br inj NEC
		804.41	Cl skl w oth fx w/o coma
		804.42	Cl skl w oth fx-brf coma
		804.43	Cl skl w oth fx-mod coma
		804.44	Cl skl/oth fx-proln coma
		804.45	Cl skul/oth fx-deep coma
		804.46	Cl skl w oth fx-coma NOS
		804.49	Cl skul w oth fx-concuss

V-Code	Description	ICD Pair	Description
		804.50	Opn skull fx/oth bone fx
		804.51	Opn skul/oth fx w/o coma
		804.52	Opn skul/oth fx-brf coma
		804.53	Opn skul/oth fx-mod coma
		804.54	Opn skl/oth fx-prol coma
		804.55	Opn skl/oth fx-deep coma
		804.56	Opn skul/oth fx-coma NOS
		804.59	Opn skull/oth fx-concuss
		804.60	Opn skl/oth fx/cereb lac
		804.61	Opn skul/oth fx w/o coma
		804.62	Opn skul/oth fx-brf coma
		804.63	Opn skul/oth fx-mod coma
		804.64	Opn skl/oth fx-prol coma
		804.65	Opn skl/oth fx-deep coma
		804.66	Opn skul/oth fx-coma NOS
		804.69	Opn skull/oth fx-concuss
		804.70	Opn skl/oth fx/menin hem
		804.71	Opn skul/oth fx w/o coma
		804.72	Opn skul/oth fx-brf coma
		804.73	Opn skul/oth fx-mod coma
		804.74	Opn skl/oth fx-prol coma
		804.75	Opn skl/oth fx-deep coma
		804.76	Opn skul/oth fx-coma NOS
		804.79	Opn skull/oth fx-concuss
		804.80	Opn skl w oth fx/hem NEC
		804.81	Opn skul/oth fx w/o coma
		804.82	Opn skul/oth fx-brf coma
		804.83	Opn skul/oth fx-mod coma
		804.84	Opn skl/oth fx-prol coma
		804.85	Opn skl/oth fx-deep coma
		804.86	Opn skul/oth fx-coma NOS
		804.89	Opn skull/oth fx-concuss
		804.90	Op skl/oth fx/br inj NEC
		804.91	Opn skul/oth fx w/o coma
		804.92	Opn skul/oth fx-brf coma
		804.93	Opn skul/oth fx-mod coma
		804.94	Opn skl/oth fx-prol coma
		804.95	Opn skl/oth fx-deep coma
		804.96	Opn skul/oth fx-coma NOS
		804.99	Opn skull/oth fx-concuss

V-Code	Description	ICD Pair	Description
		807.00	Fracture rib NOS-closed
		807.01	Fracture one rib-closed
		807.02	Fracture two ribs-closed
		807.03	Fracture three ribs-clos
		807.04	Fracture four ribs-close
		807.05	Fracture five ribs-close
		807.06	Fracture six ribs-closed
		807.07	Fracture seven ribs-clos
		807.08	Fx eight/more rib-closed
		807.09	Fx mult ribs NOS-closed
		807.10	Fracture rib NOS-open
		807.11	Fracture one rib-open
		807.12	Fracture two ribs-open
		807.13	Fracture three ribs-open
		807.14	Fracture four ribs-open
		807.15	Fracture five ribs-open
		807.16	Fracture six ribs-open
		807.17	Fracture seven ribs-open
		807.18	Fx eight/more ribs-open
		807.19	Fx mult ribs NOS-open
		807.2	Fracture of sternum-clos
		807.3	Fracture of sternum-open
		807.4	Flail chest
		807.5	Fx larynx/trachea-closed
		807.6	Fx larynx/trachea-open
		808.0	Fracture acetabulum-clos
		808.1	Fracture acetabulum-open
		808.2	Fracture of pubis-closed
		808.3	Fracture of pubis-open
		808.41	Fracture of ilium-closed
		808.42	Fracture ischium-closed
		808.43	Pelv fx-clos/pelv disrup
		808.44	Multiple closed pelvic fractures without disruption of pelvic circle
		808.49	Pelvic fracture NEC-clos
		808.51	Fracture of ilium-open
		808.52	Fracture of ischium-open
		808.53	Pelv fx-open/pelv disrup
		808.54	Multiple open pelvic fractures without disruption of pelvic circle
		808.59	Pelvic fracture NEC-open

V-Code	Description	ICD Pair	Description
		808.8	Pelvic fracture NOS-clos
		808.9	Pelvic fracture NOS-open
		809.0	Fracture trunk bone-clos
		809.1	Fracture trunk bone-open
		814.00	Fx carpal bone NOS-close
		814.01	Fx navicular, wrist-clos
		814.02	Fx lunate, wrist-closed
		814.03	Fx triquetral, wrist-cl
		814.04	Fx pisiform-closed
		814.05	Fx trapezium bone-closed
		814.06	Fx trapezoid bone-closed
		814.07	Fx capitate bone-closed
		814.08	Fx hamate bone-closed
		814.09	Fx carpal bone NEC-close
		814.10	Fx carpal bone NOS-open
		814.11	Fx navicular, wrist-open
		814.12	Fx lunate, wrist-open
		814.13	Fx triquetral, wrist-opn
		814.14	Fx pisiform-open
		814.15	Fx trapezium bone-open
		814.16	Fx trapezoid bone-open
		814.17	Fx capitate bone-open
		814.18	Fx hamate bone-open
		814.19	Fx carpal bone NEC-open
		815.00	Fx metacarpal NOS-closed
		815.01	Fx 1st metacarp base-cl
		815.02	Fx metacarp base NEC-cl
		815.03	Fx metacarpal shaft-clos
		815.04	Fx metacarpal neck-close
		815.09	Mult fx metacarpus-close
		815.10	Fx metacarpal NOS-open
		815.11	Fx 1st metacarp base-opn
		815.12	Fx metacarp base NEC-opn
		815.13	Fx metacarpal shaft-open
		815.14	Fx metacarpal neck-open
		815.19	Mult fx metacarpus-open
		816.00	Fx phalanx, hand NOS-cl
		816.01	Fx mid/prx phal, hand-cl
		816.02	Fx dist phalanx, hand-cl
		816.03	Fx mult phalan, hand-cl

V-Code	Description	ICD Pair	Description
		816.10	Fx phalanx, hand NOS-opn
		816.11	Fx mid/prx phal, hand-op
		816.12	Fx distal phal, hand-opn
		816.13	Fx mult phalan, hand-opn
		817.0	Multiple fx hand-closed
		817.1	Multiple fx hand-open
		824.0	Fx medial malleolus-clos
		824.1	Fx medial malleolus-open
		824.2	Fx lateral malleolus-cl
		824.3	Fx lateral malleolus-opn
		824.4	Fx bimalleolar-closed
		824.5	Fx bimalleolar-open
		824.6	Fx trimalleolar-closed
		824.7	Fx trimalleolar-open
		824.8	Fx ankle NOS-closed
		824.9	Fx ankle NOS-open
		825.0	Fracture calcaneus-close
		825.1	Fracture calcaneus-open
		825.20	Fx foot bone NOS-closed
		825.21	Fx astragalus-closed
		825.22	Fx navicular, foot-clos
		825.23	Fx cuboid-closed
		825.24	Fx cuneiform, foot-clos
		825.25	Fx metatarsal-closed
		825.29	Fx foot bone NEC-closed
		825.30	Fx foot bone NOS-open
		825.31	Fx astragalus-open
		825.32	Fx navicular, foot-open
		825.33	Fx cuboid-open
		825.34	Fx cuneiform, foot-open
		825.35	Fx metatarsal-open
		825.39	Fx foot bone NEC-open
		819.0	Fx arms w rib/sternum-cl
		819.1	Fx arms w rib/stern-open
		828.0	Fx legs w arm/rib-closed
		828.1	Fx legs w arm/rib-open
		810.00	Fx clavicle NOS-closed
		810.01	Fx clavicl, stern end-cl
		810.02	Fx clavicle shaft-closed
		810.03	Fx clavicl, acrom end-cl

V-Code	Description	ICD Pair	Description
		810.10	Fx clavicle NOS-open
		810.11	Fx clavic, stern end-opn
		810.12	Fx clavicle shaft-open
		810.13	Fx clavic, acrom end-opn
		811.00	Fx scapula NOS-closed
		811.01	Fx scapul, acrom proc-cl
		811.02	Fx scapul, corac proc-cl
		811.03	Fx scap, glen cav/nck-cl
		811.09	Fx scapula NEC-closed
		811.10	Fx scapula NOS-open
		811.11	Fx scapul, acrom proc-op
		811.12	Fx scapul, corac proc-op
		811.13	Fx scap, glen cav/nck-op
		811.19	Fx scapula NEC-open
V54.20	Aftrcare path fx arm NOS	733.19	Path fx oth specif site
V54.21	Aftercare path fx up arm	733.11	Path fx humerus
V54.22	Aftrcare path fx low arm	733.12	Path fx dstl radius ulna
V54.23	Aftercare path fx hip	733.14	Path fx neck of femur
V54.24	Aftrcare path fx leg NOS	733.19	Path fx oth specif site
V54.25	Aftrcare path fx up leg	733.15	Path fx oth spcf prt fmr
V54.26	Aftrcare path fx low leg	733.16	Path fx tibia fibula
V54.27	Aftrcare path fx vertebr	733.13	Path fx vertebrae
V54.29	Aftrcre path fx bone NEC	733.10	Path fx unspecified site
		733.19	Path fx oth specif site

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IV. Quality Reporting for Hospices

A. Background and Statutory Authority

Section 3004 of the Affordable Care Act amended 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 the 2014 Payment Year.

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 the 2014 payment year.

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, in the CY 2013 HH PPS proposed rule (77 FR 41548), we proposed 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 solicited comment on the proposed selection of measures.

Comment: We received six comments in support of and one comment opposed to continuing the requirement for the structural measure. We received eight comments in support of and one comment opposed to continuing the requirement for the NQF 0209 measure. The majority of commenters agreed with our proposal that no additional measures be required for Payment Year 2015 reporting. Commenters were also supportive of CMS's decision not to extend the requirement that hospices provide a list of their patient care indicators for Payment Year 2015

structural measure reporting. Some commenters raised concerns about each of the measures individually. For the structural measure, one commenter did not support the inclusion of this measure for Payment Year 2015 reporting. This commenter felt that while the measure was not burdensome to hospices, the potential of this measure to affect quality of care provided to hospice patients was questionable. We also received ten comments that did not specifically oppose the continuation of the NQF 0209 measure but did request that various aspects of the specifications of the measure be changed.

Response: While we recognize that the structural measure has limitations, it also provides CMS a nationally representative first look into the content of hospice providers' QAPI programs and provides CMS the opportunity to take that information into consideration for the future development of the quality reporting program. We appreciate the feedback on selection of the NQF #0209 Pain Measure and acknowledge potential issues with measure specifications that were detailed by commenters. Measure development and endorsement processes include the creation of measure specifications.

As a result of the comments received, we are finalizing this proposal as proposed.

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 informed decision making. The provision of quality care to hospice patients and families is of utmost importance to CMS. For annual payment determinations beyond FY 2015, 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 welcomed 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 data 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 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 welcomed comments on the potential implementation of a hospice patient-level data item set in CY 2014.

Comment: In response to our invitation to comment, we received 19 comments in support of using a standardized patient level data set, noting efforts to standardize data collection would aid in ensuring the validity of quality reporting. These comments offered suggestions on design and implementation, stressing that we should make every effort to streamline the item set so that it contains only data elements appropriate for hospice patients and required to calculate quality measures for reporting, thereby minimizing burden. Finally, most commenters were not supportive of implementing the data item set in CY 2014 due to the time needed to adequately prepare providers and other stakeholders for implementation. Commenters suggested implementing a standardized item set that would collect the data elements needed to calculate the NQF endorsed measures at least a full year prior to implementing the additional measures, or reducing the number of measures expected to be implemented at one time. We received two comments expressing opposition to the use of a standardized data set.

Response: We appreciate the comments we received about the standardized item set. We are committed to developing a Hospice Quality Reporting Program that utilizes standardized items as the basis for collecting and reporting quality measures. We have recently concluded a pilot test of a draft item set with nine hospices around the country providing services in various care settings. The main purposes of the pilot were to get a clear understanding of the process of implementation of the item set by the hospices and of the burden experienced by the hospices as they implemented the item set and collected data on patients. The quantitative and qualitative results of the pilot test will be used to inform the continued development of the item set.

Our intent is to develop an item set that would collect data elements that are already part of hospice practice and could be used to calculate the NQF endorsed QMs for hospice. We are in agreement that the item set should not add burden for patients and families and should be based on information hospices already collect as part of their patient assessment and care provision practices to the extent possible.

We will consider the suggestions offered in comment to the proposed rule as we proceed with the development and steps required to implement a standardized patient level data item set.

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 welcomed comments on the potential future implementation of these measures and the associated projected timeframe for implementation.

Comment: In response to our invitation to comment, we received 30 comments related to the list of potential future measures. Commenters were generally supportive of these measures stating that they are important areas to measure for hospices and are already being measured by many providers. Commenters also pointed out that the measures being considered are limited primarily to organizational processes related to physical symptoms. They urged the future adoption of more outcomes oriented measures. A majority of the comments advised that the list of measures focuses only on the physical realm and is missing critical elements of hospice care. They noted that the measures being considered do not accurately reflect the holistic care provided to patients and families receiving hospice services and urged CMS to consider additional measures endorsed by NQF that address the psychosocial, spiritual and patient preference aspects of hospice; fourteen commenters specifically named NQF #1641 (patient preferences) and #1647 (spiritual issues addressed). Commenters also urged CMS to consider the development of additional measures to address the shortage of endorsed measures that reflect important aspects of care such as care coordination and meeting patient preferences as pointed out by the Measures Application Partnership (MAP) report from June 2012. Most commenters supported a phased-in approach, indicating that the proposed timeline is too aggressive to allow for adequate preparation by hospice providers, vendors and other stakeholders.

Response: We appreciate the comments received about the measures being considered for inclusion in the future expansion of the Hospice Quality Reporting Program. As more measures are submitted to NQF and endorsed for use as part of quality reporting programs, we will consider these measures for future years as well. In addition, we appreciate the comments received about the need for the quality measures to reflect outcomes of care and care beyond physical symptom management. We recognize the shortage of endorsed measures that reflect the essence of high quality hospice care, and will continue to look for opportunities to work with measure developers to address this challenge.

We appreciate the comments about the timeline for implementation, and the many valid concerns hospices have about being adequately prepared, supported and trained to implement the item set and the measures. In addition, we appreciate the comments about the timeframe required for industry preparation including the work needed by vendors to help prepare for patient level data collection. We will take these comments into consideration as we further refine the implementation steps and timeline.

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 solicited comment on the succession of implementation of these two potential requirements.

Comment: In response to our invitation to comment, we received 19 comments related to use of a patient/family experience of care survey and measure. The #0208 measure, which is derived from the specific Family Evaluation of Hospice Care (FEHC) survey, was generally supported but most commenters indicated that they would only support the use of the FEHC if it were administered by a third party. Others felt third party administration is burdensome. Six commenters expressed problems with the FEHC survey, primarily that it is too long and therefore burdensome. Several commenters suggested that the survey should be electronic. One commenter opposed the use of any standardized survey.

Response: We appreciate comments received on the use of a patient/family experience of care survey and associated measure. We will utilize the suggestions offered as we proceed with the development and steps required to implement a hospice-specific patient/family experience of care survey and resulting measures.

Comment: Some commenters offered suggestions related to the succession of implementation of the two potential requirements: A standardized patient level data set and a standardized patient/family experience of care survey. Several commenters requested delay in the introduction of a data set beyond 2014. Other commenters preferred the implementation of the standardized data item set before the experience of care survey, indicating that the standardized data item set poses a greater challenge for implementation for hospices since many hospices already use the FEHC or similar survey. Some commenters preferred implementing an experience of care measure first. Two commenters suggested both be implemented in CY2014.

Response: We appreciate the comments received on the succession of implementation of these two potential requirements. We recognize the challenges associated with implementing a standardized data item set and an experience of care survey. We will carefully consider the suggestions offered as we finalize a timeline for introduction of a data set and a patient/family experience of care survey.

Summary Tables:

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TABLE 26: Finalized in the CY 2013 HH PPS Final Rule

Data Collection	Data Submission	APU Impact	MEASURES
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

TABLE 27: Target Dates

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			
Data Collection	**Data Submission**	**APU Impact**	**MEASURES**
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

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V. Survey and Enforcement Requirements for Home Health Agencies (HHAs)

A. Background and Statutory Authority

To participate in the Medicare program as an HHA provider, an agency or organization must meet the definition of an HHA in section 1891(o) of the Act. Additionally, section 1891(a) of the Act sets out specific participation requirements for HHAs, referred to as conditions of participation (CoPs), which are implemented in 42 CFR part 484. 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 CoP is specifically limited to Medicare/Medicaid beneficiaries, such as the Outcome and Assessment Information Set (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 us to meet the federal requirements for participation if they are accredited by an AO whose program is approved by us to meet or exceed federal requirements under section 1865(a). However, these deemed providers and suppliers are subject to validation surveys under § 488.7.

B. Summary of Proposed Provisions and Analysis of and Responses to Public Comments

In the following sections, we provide a brief summary of the proposed provisions, followed by our responses to public comments received on each issue. For a detailed discussion of the proposed rule, *see* the July 13, 2012 proposed rule (77 FR 41575).

1. General Provisions and Comments

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. In the July 13, 2012 proposed rule, we proposed to add new subparts I and J to 42 CFR part 488 to implement sections 1891(c) through (f) 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 the CoPs. Also, we proposed to amend certain sections of 42 CFR part 488, subpart A to include references to HHAs, where appropriate, since the current regulations only reference the survey, certification and enforcement procedures for long term care facilities. Specifically, we proposed 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 also proposed to revise § 488.3(a)(1) to include the statutory citations concerning HHAs mentioned above. In addition, we proposed to amend § 488.26 by revising paragraphs (c)(2) and (e) to include references to ''patient'' and ''patients'' which is how individuals receiving services from an HHA are referenced. Finally, we proposed to revise the heading for § 488.28 to include reference to HHAs with deficiencies. We did not receive any comments on these sections and are therefore finalizing the proposed provisions.

We received the following general comments on the proposed rule.

Comments: Several commenters stated that CMS should delay the implementation of the proposed rule until a joint CMS/Industry task force could be formed to rework the regulation and develop procedures and guidance to Regional Offices and SAs. A few commenters submitted comments in the form of procedural questions regarding SA and CMS operations to implement the regulation.

Response: We will engage industry, patient advocacy organizations, and other stakeholders in the implementation process and we will do this through the interpretive guidance process. We do not agree that an overall delay of the regulation is warranted, as this could be a lengthy delay which would only further impede implementation of an enforcement policy that is highly advisable to protect beneficiaries, aligns home health enforcement with other programs, is mandated by the Social Security Act, and is long overdue. However, we will stage the effective date of the civil money penalty (§ 488.845), the Informal Dispute Resolution (IDR) provisions (§ 488.745), and the suspension of payment for new admissions (§ 488.840) to permit more time for both dialogue and design of information system changes for effective administration of these provisions. We will also develop associated interpretive guidance that will address many of the concerns raised by commenters regarding the actual procedures that will be followed to implement the alternative sanctions. We will share proposed guidance with the HHA industry and patient advocacy organizations for comment. The effective date of the civil money penalty (§ 488.845), suspension of payment for new admissions (§ 488.840), and Informal Dispute Resolution (IDR) provisions (§ 488.745) will be July 1, 2014. The effective date of all other survey and enforcement provisions in parts 488, 489, and 498 will be July 1, 2013.

2. Subpart I—Survey and Certification of HHAs

a. Basis and Scope (§ 488.700)

We proposed in § 488.700 to specify the statutory authority for and general scope of standards proposed in 42 CFR part 488 that establishes the requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation. We are finalizing this rule as proposed. In general, this final 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.

Comments: Several commenters complimented CMS on the implementation of unannounced inspections and more specific survey protocols. Other commenters stated that the CoPs should be revised.

Response: We appreciate the comments regarding the sections of the regulation which addressed unannounced surveys and more specific survey protocols.

Regarding the comments requesting revisions to the CoPs, we appreciate the commenters concerns, but find that those comments are beyond the scope of this final rule. Any changes to the CoPs would be made through subsequent notice and comment rulemaking, to give stakeholders an opportunity to provide comments on any proposed changes.

b. Definitions (§ 488.705)

We proposed to add § 488.705 which defines 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 proposed to add definitions for these surveys at § 488.705.

In addition to those terms, we proposed 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. Except for the few modifications noted in our responses below, we are finalizing § 488.705 as proposed.

Comments: A few commenters could not tell from the definition of ''standard-level deficiency'' whether an alternative sanction could be imposed for standard-level deficiencies alone.

Response: Proposed § 488.810(b) specifically provides that alternative sanctions are applied on the basis of noncompliance with the conditions of participation. Where a condition-level deficiency is determined, an alternative sanction may be imposed. However, there may be occasions where serious noncompliance with a single standard could be cited as a condition-level deficiency, and such a finding could lead to the imposition of a sanction. For example, if a noncompliance with a standard is determined to constitute a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes, then it may be considered a condition-level deficiency. While alternative sanctions are generally not based on standard-level deficiencies alone, noncompliance with a standard that is determined to be so serious as to constitute a condition-level deficiency could result in termination from Medicare or an alternative sanction, or both.

Comment: Several commenters were unclear as to the meaning of an ''abbreviated standard survey,'' ''substandard care'' and ''extended survey.''

Response: The abbreviated standard survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, or management. It does not cover all the aspects reviewed in the standard survey, but rather concentrates on a particular area or areas of concern. The surveyor may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey or complaint. The abbreviated standard survey can be expanded and changed to a standard, partial extended or extended survey when necessary. We have revised the definition to reflect that an abbreviated standard survey may address fewer standards or conditions than a standard survey. Regarding the commenters' concerns with ''substandard care,'' we agree that the definition is not entirely clear and should be refined. In this final rule, we are clarifying the definition to explain that a finding of substandard care is a condition-level finding that is identified on a standard survey that includes one or more deficiencies which result in actual or potential harm to patients. Condition level deficiencies may also be cited based on findings of a complaint, abbreviated, extended or partial extended survey, but section1891(c)(2)(D) of the Act provides that substandard care found as a result of a standard survey will always trigger an extended survey. We appreciate that substandard care could be defined in terms of just a few CoPs rather than any CoP, and that a narrower definition would reduce the number of extended surveys. However, we consider all CoPs to be important. We regard the statutory directive for an extended survey pursuant to a finding of substandard care to mean that CMS should make a deeper inquiry (via an extension of the survey) when findings are serious, and that we ought to calibrate the extent of the inquiry to the degree of risk to patients. Therefore, we made two changes in this final rule. First, we retained the broad scope of the definition of substandard care (so as to refer to any CoP for which noncompliance was identified), but refined the definition to focus on actual harm or potential for harm to the patient. Second, we revised the definition of extended survey to state that an extended survey reviews ''additional'' rather than ''all'' CoPs that were not examined during the standard survey. Whether the extended survey then examines all, or a focused number, of the additional CoPs not examined during the standard survey can then be determined on the basis of the nature and extent of serious risk to patients that is identified in the standard survey.

c. Standard Surveys (§ 488.710)

We proposed in § 488.710, that a standard survey will 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 proposed in § 488.710(a)(1). The statute specifies that we actually visit the homes of sampled patients, and that we conduct a survey of the quality of services being provided (as measured by indicators of medical, nursing, and rehabilitative care). In proposed § 488.710(a), we specified minimum requirements and provided that visits to homes of patients will be done only with the consent of the patient, their guardian or legal representative. The purpose of the home visit is to evaluate the extent to which the quality and scope of services furnished by the HHA has 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 SA or CMS Regional Office. We had also proposed in § 488.710(b) that the survey agency's failure to follow its own survey procedures will 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 will not invalidate the underlying determinations.

Comments: Two commenters stated that CMS should conduct HHA surveys more frequently than at a minimum of every 36 months as proposed.

Response: While we agree that frequent HHA surveys are desirable, we also recognize that some HHAs have much a better history of compliance with the CoPs than others. Rather than performing more frequent surveys in every HHA, we will seek to conduct more frequent surveys of those particular HHAs for which available information indicates that they may have higher risks of quality of care problems than other HHAs. Such a more focused approach will enable us to focus our efforts and resources on those HHAs which require greater oversight and assistance.

d. Partial Extended Survey (§ 488.715)

We proposed in § 488.715 that the partial extended survey will be conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. It will 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 will 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 condition which will assist in making a compliance decision. Under § 488.24, which applies to most other providers

and suppliers and upon which this 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 to be out of compliance (and thus at a 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 will be used for HHAs. We are finalizing this section as proposed.

Comments: One commenter stated that there was no timeframe stated for the completion of a partially extended survey. The commenter recommended that CMS add a timeframe to the final regulation.

Response: A partial extended survey is conducted when (1) standard-level deficiencies are found during a standard survey and the surveyor determines that a more comprehensive review of the CoPs examined under the standard survey would result in condition-level deficiencies, or (2) it is necessary to determine if standard or condition-level deficiencies are present in the CoPs not examined in the standard survey. The standard survey can be expanded to become a partial extended survey and thus is conducted on the same interval as the standard survey. Therefore it is not necessary to add any timeframe for the completion of a partially extended survey. This is also true if a complaint or abbreviated survey identifies issues beyond the original scope of the survey. These surveys would then be considered partial extended surveys.

e. Extended Surveys (§ 488.720)

We proposed in § 488.720, that the extended survey will review compliance with conditions and standards applicable to the HHA. It could be conducted at any time, at the discretion of CMS or the SA, but will be conducted when any condition-level deficiency was found during a standard survey. The extended survey will review and identify the HHA's policies, procedures, and practices that produced the substandard care, which we define in § 488.705 as noncompliance with one or more conditions of participation at the condition-level. We regard the statutory directive for an extended survey pursuant to a finding of substandard care to mean that CMS should make a deeper inquiry (via an extension of the survey) when findings are serious, and that we ought to calibrate the extent of the inquiry to the degree of risk to patients. Whether the extended survey then examines all, or a focused number, of the additional CoPs not examined during the standard survey can then be determined on the basis of the nature and extent of serious risk to patients that is identified in the standard survey. The extended survey will 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 will review any associated activities that might have contributed to the deficient practice.

Comments: Several comments were received regarding the definition of substandard care and the association of that definition with an extended survey. In addition, as noted above in reference to § 488.710, some commenters stated that more frequent surveys should be conducted.

Response: As we noted above, in reference to the discussion of § 488.705, we have refined the definition of substandard care in § 488.705 in order to provide additional clarity. We are also clarifying the regulatory language at § 488.720, associated with the extended survey, to state that the extended survey reviews ''additional'' conditions that were not evaluated during the standard survey. The extended survey may review all conditions of participation, or may review a targeted number of conditions, that were not examined in the standard survey. We are making this refinement in response both to the request for greater clarity and to the exhortation from some commenters, previously discussed above in reference to § 488.710, that more frequent surveys be conducted. If every extended survey reviewed every condition of participation, we would consume scarce survey resources examining some conditions that are low risk in a particular HHA. The result is that we would conduct fewer standard and extended surveys than we will be able to conduct when the extended survey may focus on those additional conditions (not examined during the standard survey) that we judge to present higher risk of noncompliance compared to other conditions in the specific HHA that is being surveyed. By such judicious targeting of survey attention, we believe we will increase the surveyors' ability to identify problems that are serious and also allow us to increase frequency of surveys through targeting additional surveys where they are most needed. We have also changed § 488.720(b) to instruct that the extended survey must be conducted no later than 14 calendar days after completion of a standard survey which found the HHA was out of compliance with a condition of participation.

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 is set out at proposed § 488.725, which also provides 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, the proposed regulations at § 488.725 reflect these survey requirements. We did not receive any comments in response to our proposals in § 488.725. Therefore, we are finalizing these provisions as proposed.

g. Survey Frequency and Content (§ 488.730)

In § 488.730, we proposed to establish 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 two months of a significant number of complaints reported against the HHA (as determined by CMS), and will 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 at the discretion of CMS or the SA in order to determine compliance with the CoPs. However, under 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.

Comments: Several commenters stated that CMS should require more frequent surveys specific to complaints and substandard care issues (i.e., greater than the statutorily mandated 36 months). Commenters also suggested some complaints be investigated within 48 hours.

Response: As was stated earlier, we agree that frequent HHA surveys are desirable. However, instead of performing more frequent surveys in every HHA, we will seek to conduct more frequent surveys of those HHAs that available information indicates have a higher risk of quality of care issues. With regard to the investigation of complaints, we currently maintain a complaint tracking and prioritization system which prioritizes complaints according to the level of risk for the patients at the HHA. Complaints that indicate the possibility of an immediate jeopardy situation are given the highest priority and are investigated as soon as possible. With regard to the commenter's suggestion that complaints which indicate potential immediate jeopardy be investigated within 48 hours, we agree that prompt attention to these complaints is very important. We consider the SOM to be the most appropriate venue for specifying the timeframes by which all types of complaints should be investigated. We will take the commenter's suggestion into consideration as we develop such interpretive guidance.

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 criteria for surveyor minimum qualifications in proposed § 488.735. We are adding that the surveyor must successfully complete the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites prior to conducting an HHA survey. These prerequisites will be further explained in guidance.

In proposed § 488.735, we also set out the circumstances that will disqualify a surveyor from surveying a particular HHA as required by section 1891(c)(2)(C)(iii) of the Act. A surveyor will 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 will be prohibited from surveying an HHA if he or she has a financial interest or an ownership interest in that HHA. The surveyor will 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.

Comments: Several commenters stated that although surveyors are adequately trained and are competent, there is still inconsistency among surveyors nationally. Several commenters stated that CMS should develop formal competencies for surveyors and publish these competencies. A few commenters suggested that surveyors be tested on the competencies and skills for the program they will survey. A few commenters recommended that surveyors be required to have continuing education hours annually. A few commenters suggested that there should be additional CMS commitment of time and resources to train surveyors on the CoPs in collaboration with provider associations.

Response: We appreciate these comments regarding surveyor competencies. However, we believe that the SOM rather than the regulation should contain this level of specificity concerning surveyor competencies, and we will consider additional specification for training as we further develop the interpretive guidance. We currently require successful completion of a national HHA Basic training course (with pre-requisites) before a surveyor is allowed to survey a program independently. This is a comprehensive course and there are pre and post tests to ensure surveyor understanding. Additionally, all SAs conduct reviews of HHA surveyor work before it is released as a final set of findings. This process serves as the quality assurance for the SA. Requirements for HHA surveyor educational and experience backgrounds are determined by the SAs that employ them. Therefore, we are not accepting these recommendations.

Comments: A few commenters stated that surveyors should be disqualified if he/she worked at a competitor of the HHA being surveyed within the last two years. One commenter stated that the surveyor should be disqualified if he/she worked at any HHA within the last two years. One commenter requested clarification as to what constitutes a family member.

Response: While we appreciate the comments regarding surveyor disqualifications, we do not agree that additional criteria for surveyor disqualification beyond those specified in the statute are necessary or indicated at this time. The Act specifies at section 1891(c)(2)(C)(iii)(II), that the survey be conducted by an individual, ''who is not serving (or has not served within the previous 2 years) as a member of the staff of, or as a consultant to, the home health agency surveyed respecting compliance with the conditions of participation specified to section 1861(o) or subsection (a) of this section, and (III) who has no personal or familiar interest in the home health agency surveyed.'' Therefore, we are not accepting the recommendation for these additional requirements. In regards to the definition of ''family member,'' in the above statement, we will utilize the definition of family member located at § 411.351 in the development of interpretive guidance for this regulation. This definition includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Comment: A few commenters recommended that CMS allocate funds annually for national training of the HHA industry on the CoPs and alternative sanction policies.

Response: We appreciate the interest of the HHA industry for CMS training. We look forward to partnering with the national associations to promote knowledge and education regarding the CoPs and the provisions of this rule. We do issue periodic communications to providers and host regular open door forums to communicate important

information and engage in dialogue with the HHA industry, patient advocacy organizations, and the public. We also use webinars to train survey staff and these webinars are posted on our Web site and are available to the HHA industry. Since the recommendation to allocate funds for the HHA industry falls outside the scope of the proposed regulation, we are not accepting that aspect of the recommendation.

Comments: One commenter suggested that CMS require the use of the 2011 Survey protocols when conducting surveys to ensure consistency.

Response: Use of the survey protocols is currently our policy.

i. Certification of Compliance or Noncompliance (§ 488.740)

We proposed in § 488.740 to cross reference the rules for certification, documentation of findings, periodic review of compliance and approval, certification of noncompliance, 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 noncompliance of the HHA with the Act and CoPs.

Comment: One commenter stated that the language does not explain when or on what basis condition-level deficiencies will be identified.

Response: Guidance on how surveyors determine condition-level and standard-level deficiencies is provided in the State Operations Manual (SOM), Appendix B. These new rules do not change that practice. With the establishment of alternative sanctions, we will continue to address this issue in the development of interpretive guidance. In addition, we will consult with stakeholders prior to publication of any guidance on this issue.

Based on these comments, we are finalizing this section as proposed.

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

We proposed 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 have proposed adding an IDR process that will 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, will allow the HHA an opportunity to provide an explanation of any material submitted to the SA and respond to the reviewer's questions.

In § 488.745, we proposed to provide HHAs with the option to dispute condition-level survey findings 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, will notify the HHA in writing of its opportunity to request an IDR of those deficiencies. This notice will 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 will not postpone or otherwise delay the effective date of any enforcement action. The failure to complete an IDR will 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 will maintain the balance between an HHA's due process concerns and the public's interest in the timely correction of HHA deficiencies.

Comments: Several commenters applauded our introduction of an Informal Dispute Process (IDR) but added that CMS should delay the imposition of a sanction until the completion of the IDR process.

Response: We do not agree with the commenters regarding a delay of the imposition of a sanction until after IDR is completed. Section 1891(f)(3) directs us to ensure that our procedures for imposing sanctions be designed so as to minimize the time between identification of deficiencies and imposition of the sanctions. We are providing for IDR beginning with the provider's receipt of the official Statement of Deficiencies, in order to give facilities an opportunity to rebut survey findings early in the process. While IDR is not required under the statute, by adding this feature to the enforcement process we are balancing the needs of agencies to avoid unnecessary disputes and protracted litigation, on one hand, with the interests of HHA patients, which we believe to be paramount, in assuring the most rapid correction of deficiencies. The IDR is meant to be an informal process whereby the provider has an informal opportunity to address the surveyor's findings, either by disputing them or providing additional information. This process is offered immediately after the survey and a request for IDR must be made within the same 10 calendar day period that the HHA has for submitting a plan of correction, as we provide in § 488.745(d). In those occasions where an IDR may occur after a remedy is imposed, the IDR will still be conducted in time for the IDR results to be taken into account in the remedial action. In the case of civil money penalties that may be imposed with an accrual effective date beginning on the last day of the survey, we explicitly provide at § 488.845(f) that the due date for the collection of a CMP is 15 days after a final administrative decision. This provides time for an IDR or administrative hearing to take place before the due date for collection. We also specify at § 488.745(c) that if any findings are revised or removed by CMS or the state (for surveys conducted by the SA) based on IDR, the CMS–2567 is revised accordingly. Furthermore, if CMS accepts the SA's revised CMS–2567 and any enforcement actions imposed solely as a result of those cited deficiencies, CMS will adjust such enforcement actions accordingly.

Comments: Several commenters referenced the IDR process as an independent dispute resolution and submitted comments regarding the use of third parties not associated with the SA. One commenter stated that the HHA could share the cost of the independent dispute resolution.

Response: We wish to provide clarification for these commenters. The proposed rule discussed ''informal dispute resolution'' and not independent informal dispute resolution. The proposed process will be conducted internally by the SA or CMS as indicated. Each SA is responsible for setting up its own IDR process. We do not preclude SAs from involving independent contractors.

Comments: Several commenters stated that the IDR process should be

available for standard-level deficiencies as well as condition-level deficiencies.

Response: We thank the commenters for this recommendation. However, we do not agree that the IDR process should be expanded to standard-level deficiencies. The purpose of the IDR is for the HHA to dispute condition-level findings that may be the impetus for an alternative sanction. Standard-level findings alone do not trigger an alternative sanction. Some findings of noncompliance with specific standards (that is, standard level findings), however, may be cited at the condition-level if they are repeat deficiencies or are evaluated as being extremely serious. If noncompliance is cited at the condition-level, such condition-level classification will be clearly communicated to the HHA and will be accompanied by rights to request an IDR as well as appeal. Additional guidance will be provided in survey protocols.

Comment: Several commenters requested further clarification of how the IDR process will be implemented.

Response: We understand the interest of the commenters in specific procedures for the implementation of the IDR process. CMS will develop them as a part of the interpretive guidance associated with the final regulation.

Comments: Several commenters requested specific timeframes for the IDR process due to the delays that may occur at the SA level in getting the Statement of Deficiencies to the HHA.

Response: We agree that these timeframes are essential to the effective implementation of the IDR process. We will develop these instructions through interpretive guidance, internal policy directives and SA performance standards.

Comments: A few commenters requested that CMS expedite the IDR process.

Response: We agree that timeframes for the expeditious accomplishment of the IDR process are essential. We will develop instructions through interpretive guidance, internal policy directives and SA performance standards.

Comments: One commenter recommended that the patient, their representative and the State ombudsman should be notified of the IDR so that they might provide valuable input into the IDR process.

Response: We understand the interest voiced by the commenter. The IDR process is provided primarily as an opportunity for the provider to provide additional information and to dispute condition-level deficiencies. This is not an adversarial setting and it will not be necessary for the SA or CMS to seek additional input from other parties. However, we will consider the inclusion of such members in interpretive guidance as appropriate.

Comments: One commenter felt the 10 day response time required for the provider to request IDR and submit evidence was too brief.

Response: We appreciate the concern of the commenter regarding the response time provided. However, because of the need to address disputed findings timely and enable the provider to begin corrections to regain compliance as soon as possible, we do not feel that a shorter time period will be prudent.

Based on the comments above, we are finalizing this section as proposed.

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

a. Statutory Basis (§ 488.800)

We proposed to add 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 proposed to set out the statutory basis for the new subsection at § 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, we proposed that 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.

Comments: Two commenters stated that CMS had exceeded the authorization of the statute with the extensive sanctions, the excessive amounts of civil money penalties and dependence on the subjective determinations of state surveyors. Another commenter stated that CMS improperly, and without statutory authority, limits enforcement to condition-level deficiencies.

Response: We do not agree that the alternative sanctions in this final rule exceed the authority of the statute. Section 1891(f)(1)(A) directs the Secretary to develop a range of sanctions to impose on a HHA that is not in compliance with the federal requirements, which must include civil money penalties, suspension of payments for new admissions and temporary management. We do not believe that this is an exhaustive list. Therefore we are adding through rulemaking two additional sanctions to be included within that range of sanctions. Under the HHA enforcement context, we have added the additional remedies of directed plan of correction and directed in-service training, which have both been successfully used in our enforcement of the nursing home requirements. In our experience with skilled nursing facilities, we realize that some compliance problems are a result of imperfect knowledge on the part of health services staff relative to state-of-the-art practices and resident outcome expectations. This is also the case with services provided to HHA patients. We believe that the HHA provider would benefit from a directed in-service training program conducted by sources

with an in-depth knowledge of the area(s) which require specific training so that positive change is achieved and maintained. Similarly, under a directed plan of correction, an HHA would be guided by individuals with knowledge of necessary corrective actions (for example, us, the SA, or a temporary manager (with CMS approval)) to ensure that the underlying cause of cited deficiency or deficiencies does not recur. This remedy sets forth the expected correction actions which an HHA must take to achieve compliance and the dates by which the actions must be taken.

We disagree with the comment that the proposed rule limits the enforcement to condition-level deficiencies without statutory authority. Section 1891 does not specify the level of noncompliance that would trigger the imposition of an enforcement remedy; rather, it provides that remedies are to be imposed when an HHA is not in compliance with the requirements of section 1861(o) and 1891(a), which includes implementing regulations at Part 484. We consider an HHA to be in substantial compliance with the CoPs when all deficiencies cited are at a standard-level. Thus it will not be consistent for CMS to impose alternative sanctions based upon standard-level deficiencies alone when the HHA is considered to be in compliance with the CoPs.

Comment: Several commenters stated that, because of the risk that sanctions could cause HHAs to close, CMS should either not implement the sanctions at all or should progressively implement the sanctions that are non-monetary sanctions first and then later implement monetary sanctions (civil money penalties and suspension of payment). Another commenter stated that CMS should only impose alternative sanctions in situations where an HHA has shown reckless disregard of its responsibilities or intentionally ignored its compliance obligations. One commenter stated that the statute allowed CMS the discretion to impose sanctions incrementally. One commenter stated that no sanction should be imposed when the natural and foreseeable outcome of the sanction(s) is closure of the agency. One commenter stated that sanctions are meant to be an alternative to the ''death-knell penalty'' of termination.

Response: We appreciate the concerns of the commenters that alternative sanctions may cause HHAs to close, although we believe that risk to be lower than the risk of closure if the alternative were not available and CMS terminated Medicare participation altogether. Alternative sanctions allow providers who have been cited for noncompliance to make the necessary corrections to achieve compliance and avoid termination from the Medicare program. There is a range of sanctions available which we may impose based upon the nature and severity of the noncompliance. Because it is not our intent that alternative sanctions force HHA closure, we have made revisions to the CMP amounts by expanding the ranges within the regulatory text so as to permit CMS greater flexibility in correlating amount of the CMP with the extent and seriousness of noncompliance. Additional information will be provided in interpretive guidance. We must terminate any HHA provider who is not in compliance with the CoPs at the end of 6 months following the imposition of an alternative sanction. With regard to the suggestion of incremental sanctions, the statute at section 1891(f)(1) allows a range of possible sanction options. Our policy is generally one of progressive action. We will be developing guidance for this process in the SOM. Development of guidance also provides an appropriate opportunity to engage stakeholders in the process and we will do so. Section 1891(f)(1) of the Act requires that we develop and implement a range of sanctions to include at minimum civil money penalties, suspension of payments for new admission and temporary management. Incremental imposition of sanctions and choice of specific sanctions will be discussed in the interpretive guidance.

Comment: Several commenters stated that CMS should only impose alternative sanctions after one or more survey revisits validate that compliance has not been re-gained by the agency.

Response: We do not agree that the imposition of sanctions should always be delayed until after revisits are conducted. Many of the alternative sanctions, such as civil money penalties and suspension of payments that are imposed upon a finding of noncompliance will end only upon an HHA's correction. This process was intended to prompt immediate correction. An important goal of the alternative sanctions is to encourage more expeditious correction of any noncompliance with the conditions of participation.

Comment: One commenter stated that the contentious nature of the alternative sanctions may damage the relationship between CMS and the HHA industry.

Response: We work to maintain an open and positive relationship with the HHA industry. These sanctions, which are statutorily required, are established with the purpose of increasing compliance by the HHAs with the CoPs, which is a goal which we share with the HHA industry. We plan to continue dialogue with all stakeholders as we prepare for implementation.

Comment: Several commenters were concerned that CMS is implementing alternative sanctions for HHAs using 26 years of, ''flawed experience with nursing home enforcement.''

Response: We have found that the nursing home enforcement sanctions have been instrumental in addressing and changing compliance in the nursing home industry. By using our experience with the nursing home sanction program in the development of the HHA sanctions, we were able to identify those concerns and issues which will require specific interpretive guidance and more consistent application of the sanctions.

Comments: Several commenters stated that the alternative sanctions will drive surveyors to cite deficiencies at a higher level in order to increase revenue for the SA. One commenter stated that the sanctions would change the role of the surveyor from one of educator/partner to a bounty hunter.

Response: Determinations on whether to impose alternative sanctions and the specific sanction to be imposed will not be left to the sole discretion of an HHA surveyor. First, condition-level-findings by the surveyor are reviewed by the SA Office before the SA sends their noncompliance certification and enforcement recommendation to the CMS RO. Second, all final decisions regarding whether or not to impose a sanction and what type of sanction to be imposed, will be made by the applicable CMS RO. Any funds collected as a result of civil money penalties imposed upon an HHA are distributed to the state Medicaid Agency and to the US Treasury under section 1128A(f) and § 488.845(g). In order to avoid any appearance that the imposition of sanctions would become a revenue source, it is our policy under this rule in § 488.845(g)(2) that no penalty funds may be utilized for survey and certification operations or as the state's Medicaid non-federal medical assistance or administrative match. We believe these are effective protocols to safeguard the integrity of the HHA enforcement process.

Comment: Several commenters stated that CMS should do joint and recurring training courses on alternative sanctions with the HHA industry, Accrediting Organizations and surveyors.

Response: We appreciate this recommendation. We will provide this training through a web based

application and provide for additional dialog with stakeholders.

Based on the comments above, we are finalizing this section as proposed.

b. Definitions (§ 488.805)

We proposed in § 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 final rule uses ''alternative sanctions,'' which we consider to have the same meaning.

Based on the comments below, we are revising the definitions for ''repeat deficiency,'' and ''temporary management'' and are finalizing the remaining definitions as proposed.

Comments: Several commenters requested that CMS clarify the meaning of ''repeat deficiency'' and ''immediate jeopardy'' as well as ''temporary management.''

Response: We agree that the proposed definition of ''repeat deficiency'' was somewhat confusing and have revised the regulatory text to further clarify that ''repeat deficiency'' means a condition-level deficiency cited on the survey that is substantially the same as or similar to, a finding of standard-level or condition-level deficiency citation issued on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Additionally, we will publish further guidance in the SOM to surveyors for identifying and citing repeat deficiencies. Current CMS policy on the determination of immediate jeopardy has been in effect for a significant period of time and clearly defines the criteria for such a determination. Generally, immediate jeopardy situations are infrequent in HHAs. For example, there were only 11 immediate jeopardy determinations cited in 2011, during the course of over 5,500 surveys of HHAs. Based upon our experience, the existing guidance in the SOM, and the infrequency of this determination, we believe the definition of immediate jeopardy is sufficiently clear. Regarding the definition of temporary management, we have revised the definition to provide clarity that the governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA to correct deficiencies identified in the HHA's operations.

c. General Provisions (§ 488.810)

We proposed in § 488.810 the 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, will be based on condition-level deficiencies, found in an HHA during a survey. We will 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 the Medicare program. 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 found by the SA during a complaint or validation survey and that remain uncorrected, oversight of that HHA is transferred to CMS, through the SA. In such a case where deemed status is removed, we will follow the usual procedures for such oversight, as indicated in sections 3257 and 5100 of the SOM, and under the processes in this final rule, as appropriate. Once a sanction is imposed on an accredited HHA and deemed status is removed, oversight and enforcement of that HHA will be performed by the SA and not the accrediting organization, until the HHA achieves compliance and the alternative sanction(s) is removed or until the HHA is terminated from the Medicare program.

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

Comments: We received one comment requesting clarification of the regulation text at § 488.810(d) pertaining to the application of sanctions to subunits, particularly the second sentence.

Response: We agree that the second sentence of the regulation text of this section of the proposed rule was confusing and unnecessary, so we have removed the second sentence for clarification.

We proposed in § 488.810(e) that an HHA that is not compliant with the CoPs will be required to submit an acceptable plan of correction (POC) to CMS. We defined plan of correction in § 488.805 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 that specifies the date by which those deficiencies will be corrected. A POC is required for any deficiency, whether it is at the condition-level or standard-level. More specifically, a POC will detail how an HHA has or will correct each deficiency, how the HHA will act to protect patients in similar situations, how the HHA will ensure that each deficiency does not recur, how the HHA will monitor performance to sustain solutions, and in what timeframe corrective actions will be taken by the HHA. We will determine if the POC was acceptable based on the information presented in the POC.

We proposed in § 488.810(f) that we will provide written notification to the HHA of our intent to impose a sanction. This notice will specify the specific sanction, the statutory basis for the sanction, and appeal rights. The notice periods specified in § 488.825(b) and § 488.830(b) begin the day after the HHA receives the notice.

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 § 488.845(f).

Comments: Several commenters requested additional clarification regarding our statement that the SA

would follow ''usual procedures'' when an accredited HHA loses its deemed status due to uncorrected condition-level deficiencies.

Response: For HHAs who are accredited by an AO with a CMS-approved program, the SA and CMS may still conduct complaint surveys or validation surveys of these agencies. Condition-level deficiencies may be cited by a SA or CMS Regional Office during a complaint investigation or validation survey of a deemed agency. In these cases, the SA or Regional Office removes deemed status of the agency and the SA or Regional Office resumes oversight activity of this provider. We may impose alternative sanctions or begin termination proceedings of the accredited HHA just as we do with a non-deemed agency.

Based on the comments below, we are finalizing this section as proposed.

Comment: Several commenters stated that deemed HHAs receive an unfair advantage as they are allowed a sanction free opportunity to correct before termination and alternative sanctions are not applied.

Response: While CMS-approved AOs may have a different approach in enforcement actions, agencies will still face enforcement actions, including termination, by us for noncompliance. Under § 488.8(a), CMS reviews and evaluates an AO for, among other things, the equivalency of the AO's accreditation requirements to that of CMS's requirements and the comparability of the AO survey procedures to those of the SA. Additionally, the AO must agree to provide CMS with a copy of the most current accreditation survey report together with any other information related to the survey as we may require (including corrective action plans). Furthermore, AOs notify us in writing within 10 days of a deficiency cited during an AO survey where the deficiency poses an immediate jeopardy to the patients or a hazard to the general public. In addition, we perform validation and complaint surveys of accredited providers. If a condition-level finding is cited during a complaint or validation survey, the HHA loses deemed status and oversight is resumed by the SA or Regional Office and the HHA will then be subject to imposition of alternative sanctions.

Comments: A few commenters stated that any condition-level finding that leads to the imposition of a sanction at a sub-unit (that is not a branch office) should have that sanction be applied against the parent as a business entity as well.

Response: We disagree with the commenters. Sub-units are considered independent entities for the purpose of Medicare Provider Enrollment and have separate certification numbers and separate provider agreements from the parent HHA. Sub-units are independently required to meet the CoPs and thus any sanctions imposed for deficient practices would apply only to that sub-unit.

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

Section 1891(e)(2) of the Act provides that if we find 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, we may terminate the provider agreement, impose an alternative sanction(s), or both, at CMS's discretion, for a period not to exceed 6 months. The choice of any alternative sanction or termination will reflect the impact on patient care and the seriousness of the HHA's patterns of noncompliance and will be based on the factors proposed in § 488.815. We could impose termination of the provider agreement (that is, begin termination proceedings that would become effective at a future date, but not later than 6 months from the determination of noncompliance) 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 timeframe of 6 months, whether or not the violations constituted an ''immediate jeopardy'' situation. We proposed in § 488.815, 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, which 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 will 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.

Based on the comments below, we are finalizing this section as proposed.

Comment: Several commenters stated that CMS should include requirements that decision makers be subject to rigorous training on established standards. Other commenters wanted more specific clarity on how decisions will be made in order to promote consistency.

Response: We appreciate the commenter's requests for more detailed instruction on the selection of sanctions. We will provide greater details in interpretive guidance that will be developed for the regulations. We will also provide extensive training for our SAs and Regional Offices on the factors for the selection of sanctions.

Comment: Several commenters stated that the factors related to quality of care issues are vague.

Response: Because each determination that an HHA agency has failed to provide quality patient care is unique, based on individual patient and agency observations and occurrences, we are not able to include an all inclusive listing of such failures within the regulation. Therefore we will not accept this recommendation.

Comment: Several commenters did not agree that the fact that the HHA is part of a larger organization should be included as a factor to be considered in the selection of sanctions.

Response: We included this factor to address those situations where the policies of the umbrella organization may be incompatible with the unique operation of the HHA to the extent of causing noncompliance.

Comments: Several commenters questioned why a system wide-failure was included as a factor in the selection of alternative sanctions.

Response: We included the system-wide failure as a relevant factor because such a failure may indicate that the current HHA administration is not able to make the needed corrections. Furthermore, temporary management directed in-service and directed plan of correction may be crucial in order for the HHA to make necessary corrections to regain compliance.

Comments: One commenter stated that CMS should consider access to care as a factor in the selection of sanctions.

Response: While we are always mindful of access to care concerns, it is unlikely that access to additional HHAs would not be available should a

sanction make an agency temporarily or permanently unavailable for new admissions. An important goal of alternative sanctions is to encourage more expeditious compliance with the CoPs regardless of access issues. We do not believe that patients in remote areas should be accorded any less quality of care than patients in other areas.

Section 1891(f)(3) of the Act provides for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. We 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 on the most recent previous standard survey or any intervening survey since the most recent standard survey. Any standard-level findings will be evaluated for condition-level noncompliance based on the HHA's failure to correct and sustain compliance. As noted in 488.815(c), we will consider the presence of repeat deficiencies as a factor in selecting sanctions and civil money penalties.

Based on the comments below, we are finalizing this section as proposed.

Comments: Several commenters stated that the definition of ''repeat deficiency'' was not clear. The commenters wanted to know if the same tag had to be cited, what time frame was referenced and if standard-level deficiencies would cause the imposition of sanctions.

Response: We appreciate this comment and have revised the definition of ''repeat deficiency'' to clarify that a repeat deficiency is a condition-level citation that is the same as, or similar to, a previous standard or condition-level deficiency cited on the most recent previous standard survey or any intervening survey since the most recent standard survey. Further information will be provided in guidance as it is developed. This guidance will be shared with stakeholders for comment.

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 is no longer in compliance with the CoPs. Section 1891(f)(2) of the Act explicitly provides for the following sanctions to be included in the range of sanctions: Civil money penalties, suspension of payment for new admissions, and temporary management. We proposed in § 488.820 those specific alternate sanctions and we are finalizing them in this final rule. In addition to those specified in the statute, we are adding the following additional alternative sanctions: A directed plan of correction and directed in-service training. The list of alternative sanctions that could be imposed for a noncompliant HHA is in § 488.820.

Based on the comment below, we are finalizing this section as proposed.

Comments: One commenter requested that CMS develop a tracking system for alternative sanctions.

Response: CMS has developed a tracking system for alternative sanctions in long term care within our automated survey system (ASPEN) and plan to expand this system to include alternative sanctions for home health.

f. Actions When Deficiencies Pose Immediate Jeopardy (§ 488.825) and Termination (§ 489.53)

Under section 1891(e)(1) of the Act, if CMS determines that an HHA's deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to remove the immediate jeopardy situation and prompt correction of the deficiencies by imposing a sanction or terminating the HHA's certification, or both. We proposed in § 488.825(a) to implement the statutory requirement by specifying that if the immediate jeopardy situation is not addressed and resolved within 23 days from the last day of the survey because the HHA is unable or unwilling to correct the deficiencies, CMS will terminate the HHA's provider agreement. In addition, CMS could impose one or more other alternative sanctions including a civil money penalty (CMP), temporary management and/or suspension of all Medicare payments before the effective date of termination. We proposed these provisions in § 488.825.

We also proposed in § 488.825(b) a two day notice requirement for sanctions, except for civil money penalties, that are imposed when there is an immediate jeopardy situation. For terminations, we will give notice of the termination within 2 days before the effective date of the termination, as we proposed in § 489.53(d)(2)(iii), which is consistent with the requirement for skilled nursing facilities in § 489.53(d)(2)(ii). Under our existing 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 will 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 will terminate the provider agreement no later than 23 days from the last day of the survey. We proposed to amend § 489.53 by adding a new basis for termination at paragraph (a)(17), establishing that we will 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 at § 488.825(b) will include the nature of the noncompliance, the sanctions to be imposed, the effective date of the sanction, and the right to appeal the determination leading to the sanction. In order to assure an HHA achieved prompt compliance, we expect that we will 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 § 488.825(c), we will 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 will be responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The state will be required to assist the HHA with this process. This is consistent with existing regulations at § 488.55(a)(2) providing for payments to be made up to 30 days for HHA services furnished under a plan established before the effective date of termination.

Based on the comments below, we are finalizing these sections as proposed.

Comments: Several commenters stated that HHAs do not have control over the patient's home environment and accordingly immediate jeopardy situations identified in the patient's home cannot be considered to be under the control of the HHA.

Response: We disagree with the commenters and note that generally most immediate jeopardy findings made against a certified HHA are based upon actions that either the HHA took or failed to take to meet the CoPs, such as failure to take patient care actions which were indicated by either the care plan for the patient or current standards of practice. Other situations that may cause immediate jeopardy may include, but are not limited to, situations listed in current CMS guidance, located in the SOM, Appendix Q.

Comments: Several commenters stated there is confusion as to the definition of immediate jeopardy and the difference between immediate

jeopardy and condition-level findings. Several commenters also expressed a concern that the determination of immediate jeopardy is surveyor dependent.

Response: Our policy on the determination of immediate jeopardy has been in effect a considerable length of time and is clear that patient (even one patient) health and safety must be at risk of injury or harm to support the determination. (See SOM Appendix Q). Surveyor findings which indicate a possible finding of immediate jeopardy are vetted by the state and CMS Regional Office before the final determination is made. Thus, a finding of immediate jeopardy is not made by the surveyor in isolation. As a general matter, immediate jeopardy determinations occur infrequently in home health agencies. For example, there were only 11 immediate jeopardy determinations in HHAs made in 2011.

Comment: A few commenters asked that CMS reconsider the 2 day notice of termination with an immediate jeopardy finding.

Response: The 2 day termination notice for immediate jeopardy findings is a long standing CMS policy that has been successful with other providers and has been used with immediate jeopardy determinations of HHAs for many years. We find that the 2 day notice is prudent considering the short 23 day time frame to attain compliance and also given the serious risk to patient health and safety. The purpose of the 2 day notice is to inform the HHA of the immediate jeopardy situation, its egregious nature and that the HHA will be terminated in 23 days unless the immediate jeopardy is corrected.

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, the provisions we proposed at § 488.830 reflect this enforcement policy and address the definition of ''noncompliance,'' the requirement of 15 day notice of sanctions, the criteria for continuation of payment, and the termination time frame when there is no immediate jeopardy.

Section 1891 of the Act does not require CMS to discontinue alternative sanctions when it also proposes to terminate an HHA's participation in Medicare; thus, these sanctions, as finalized, will continue while we initiate 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 will apply until the HHA achieves compliance or has its Medicare participation terminated, whichever occurs earlier. For example, the suspension of payment sanction will end when the HHA corrected all condition-level deficiencies or was terminated from the program.

We proposed in § 488.830(b) that for a deficiency or deficiencies that do not pose immediate jeopardy, we will give the HHA at least 15 days advance notice of any proposed sanctions, except civil money penalties (which is discussed below under § 488.845), which will 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. Sections 488.830 to 488.865, describe each possible sanction and procedures for imposing them.

Finally, in § 488.830(e), we will 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 will be responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The state will be required to assist the HHA with this process.

Based on the comments below, we are finalizing § 488.830 with minor technical modifications for grammar.

Comments: Several commenters recommended that CMS not impose any sanction until the HHA had received revisits from the survey agency and the determination was made that the HHA had not corrected the noncompliance even after an opportunity to correct.

Response: We do not agree that the imposition of alternative sanctions should be delayed until after the conclusion of revisits. The primary goal of alternative sanctions is to encourage more expeditious correction of noncompliance. Such a delay as the commenter recommends will not be consistent with the intent of the statute.

h. Temporary Management § 488.835

We proposed in § 488.835 when and how we apply temporary management, the duration and effect of this sanction, and the payment procedures for temporary managers' salaries and other additional costs. As we provide in § 488.805, 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 and § 484.14(c)) who will be under the direction of the HHA's governing body and who will 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 will 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 will impose temporary management to bring an HHA into compliance with program requirements in non-IJ cases within 6 months, as we indicate in § 488.835(c). We will also choose to impose temporary management as a sanction for deficiencies that pose immediate jeopardy to patient health and safety, as permitted under § 488.825(a)(3).

The individual appointed as a temporary manager will be required to have work experience and education that will qualify such individual to oversee the correction of deficiencies so that the HHA could achieve substantial compliance with the Medicare requirements. Each SA will maintain a list of recommended individuals who will be eligible to serve as temporary managers, and annually submit the list to CMS.

If the HHA refuses to relinquish authority and control to the temporary manager, we will 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 will be terminated. Additionally, if the HHA resumes management control without CMS's approval, it will be deemed to be

a failure to relinquish authority and control to the temporary manager and we will impose termination and could impose any additional sanctions. The appointment of a temporary manager will not relieve the HHA of its responsibility to achieve compliance. We proposed in § 488.835(c) that temporary management will end when:

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

We believe that § 488.805 and § 488.835 will provide the temporary manager with the authority necessary to manage the HHA and cause positive changes. The temporary manager will 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. Furthermore, temporary management will be provided at the HHA's expense. Before the temporary manager is installed, the HHA will 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 though such temporary outside management might be necessary in some cases to bring the HHA back into compliance with the conditions of participation. We have indicated that the salary for the temporary manager will 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 will have to pay for any additional costs that will 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 will be considered by CMS to be a failure to relinquish authority and control to temporary management.

Comments: There were numerous comments expressing opposition to the use of temporary management as an alternative sanction. Some commenters stated that this takes control away from the HHA Governing Body. Some commenters stated that temporary manager should be allowed control only over the CoPs.

Response: Section 1891(f)(2)(A) of the Act requires the Secretary to include temporary management as an available alternative sanction for non-compliant HHAs. This particular sanction will be used in situations where the current administration of the HHA has demonstrated an inability to achieve or maintain compliance with the CoPs. The HHA accepts the alternative sanction in lieu of immediate termination from Medicare and agrees to relinquish the operation of the agency to a qualified temporary manager. The temporary manager works under the direction of the HHA Governing Body to take whatever actions are indicated to regain compliance with the CoPs.

Based on the comments below, we are finalizing this section as discussed below. We note that we are replacing the term ''deficiency'' used in the proposed rule at § 488.835(a)(1) with ''noncompliance'' in this final rule as a technical modification.

Comments: Several commenters expressed concern about the liability of the HHA when a temporary manager is appointed and assumes control.

Response: The temporary manager works under the direction of the HHA's existing Governing Body, which has ultimate liability responsibility. Therefore, we do not agree that this sanction creates new liability for the HHA.

Comment: Several commenters expressed concern regarding the availability and costs of the temporary manager.

Response: CMS policy places the responsibility upon each SA to ensure the availability of qualified temporary managers by maintaining of list of possible candidates. We maintain that it is critical that temporary managers be reimbursed at prevailing rates in order to ensure qualified candidates. The cost of the temporary manager must be borne by the HHA as a component of their inherent management responsibilities.

Comments: One commenter recommended that CMS use temporary management in only extraordinary circumstances, that any temporary manager be bonded and that the HHA be given the choice of three possible temporary managers.

Response: We will develop interpretive guidance for this provision that will provide specific direction to the SAs and Regional Offices. This guidance will emphasize that temporary management is used to address situations where the current management of the agency has shown an inability to achieve or maintain compliance with the CoPs. We do not agree that it is necessary to add a requirement to this regulation that the temporary manager be bonded.

Comments: One commenter recommended that CMS impose no additional sanctions in conjunction with temporary management. They also recommended that CMS not terminate the HHA if the temporary manager is at fault for not bringing the HHA back into compliance.

Response: Section 1891 of the Act does not prohibit the concurrent imposition of more than one sanction. For example, it may be appropriate for the appointment of a temporary manager to be imposed in combination with a directed plan of correction. We do not agree that the HHA should not be terminated if the temporary manager fails to bring the agency back into compliance. The failure may be due to the HHA's policies, processes, or procedures or issues outside the control of the temporary manager. The agency can accept this alternative sanction in lieu of termination as a method to promptly regain compliance with the requirements. Section 1891(e) of the Act requires that no alternative sanction may be in effect for a period of more than 6 months and thus must be terminated if compliance is not achieved within this 6 month window of the sanction.

Comment: Several commenters objected to the regulation at § 488.835(d)(3) where we indicated that we would not allow the costs of the temporary manager as an allowable cost on the cost report.

Response: We agree and are removing § 488.835(d)(3). Removal of this prohibition is also responsive to concerns from several commenters about the potential for sanctions to cause closure of a HHA, and is consistent with CMS treatment of temporary managers in nursing homes.

i. Suspension of Payment for all New Admissions and New Payment Episodes (§ 488.840)

We proposed in § 488.840 provisions describing when and how we would apply a suspension of payment for new Medicare admissions and new PPS episodes of care. If an HHA has a condition-level deficiency or deficiencies (regardless of whether or not immediate jeopardy exists), we may 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 will be for a period not to

exceed 6 months and will end when the HHA either achieved substantial compliance or was terminated. We will provide the HHA with written notice of our intent to impose this sanction at least 2 calendar days before the effective date of the sanction in immediate jeopardy situations (§ 488.825(b)) or at least 15 calendar days before the effective date of the sanction in non-immediate jeopardy situations (§ 488.830(b)). Our notice of suspension of payment for new admissions and new payment episodes will generally include the following: the nature of the noncompliance; the effective date of the sanction; and the right to appeal the determination leading to the sanction.

We added the definition of a ''new admission'' in § 488.805 to mean an individual who becomes a patient (is admitted) or readmitted to the HHA under Medicare on or after the effective date of a suspension of payment sanction. We proposed to expand the definition of ''new admission'' to include new payment episodes because we believed 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 but are not discharged will be considered neither a new admission nor will the resumption of their services 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 will end when the HHA was determined to have corrected all condition-level deficiencies, or upon termination, whichever is earlier.

Before the suspension becomes effective, we will notify the HHA of the imposition of this sanction under § 488.840(b)(1). Once such a sanction is imposed, the HHA will be required to notify any new patient admission and patients with new payment episodes that Medicare payment will not be available to this HHA because of the imposed suspension before care could be initiated. Moreover, the HHA is 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 may not be available. The suspension of payment will end when we terminate the provider agreement or CMS finds the HHA to be in compliance with all CoPs.

In § 488.840(b)(3), if we terminate the provider agreement, or if the HHA achieves substantial compliance with the CoPs (as determined by CMS) thereby ending the suspension period, the HHA will 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 is 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 have interpreted the term ''suspend'' to mean to temporarily stop Medicare payments, without the possibility of recovering the suspended payments. Once compliance with the CoPs is achieved after the suspension takes effect, we will resume payment to the HHA prospectively from the date that CMS determines correction.

We proposed in § 488.840(c) that the suspension of payment will end either when we terminate the provider agreement or when we find the HHA to be in substantial compliance with all of the CoPs. Based on the comments below, we have modified this section as noted below and have also modified the proposed definition of ''new admission'' in § 488.805 to reflect the modifications under this section.

Comments: Two commenters agreed that the imposition of suspension of payment for new admissions to the agency as well as suspension for new payment episodes for patients already being seen by the agency would be effective as alternative sanctions. However, the vast majority of commenters responded that the use of payment suspension for new payment episodes would be detrimental to the agency in their efforts to make corrections necessary to confirm compliance and would be disruptive to patients.

Response: We appreciate these comments and agree that the use of suspension of payment for new patient admissions would be an effective sanction while suspension of new payment episodes may be disruptive to patients as they would have to transfer to different HHAs with different staff. It would also be difficult for the HHA to maintain a caseload of patients to ensure compliance with requirements. Therefore, we will keep the suspension of payment for new patients as an option, but remove references to new payment episodes from the suspension of payment sanction as well as the definition of ''new admission'' in § 488.805.

j. Civil Money Penalties (CMPs) § 488.845

We proposed in § 488.845 provisions 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.

Comment: Many comments were received stating the belief that decisions about imposition of and amounts of CMPs imposed will be at the discretion of individual surveyors and that this would lead to adversarial and contentious relationships.

Response: We appreciate the comments and repeat that decisions regarding whether to impose alternative sanctions and the specific sanction to be imposed will not be left to the HHA surveyor alone. First, condition-level-findings are vetted at both the state and Regional level. Second, all decisions regarding whether to impose a sanction and the type of sanction to be imposed, will be made by the applicable CMS Regional Office.

Comments: Additional comments were received requesting clarification of when CMPs would be imposed.

Response: We have set forth the framework for the imposition of CMPs. Further instructions will be published in interpretive guidance.

Comments: Many comments were received reflecting that the proposed amounts of CMPs were excessive; would put HHAs out of business; would take away funds from indigent care; would affect access to care in rural areas and should not be imposed prior to the end of the appeal process.

Response: It is not our intent to put agencies out of business through the use of alternative sanctions. CMPs are an effective sanction because HHA's are subject to its financial impact. The CMPs are an incentive for the HHA to promptly correct the noncompliance.

Per day CMPs carry a built-in incentive to correct noncompliance promptly since the faster the correction the sooner the CMP can stop accruing. It is also our intent when imposing alternative sanctions to provide agencies with time to correct any condition-level noncompliance and thus avoid the interruption of services to patients that might occur if the HHA were to be terminated from Medicare. It is the responsibility of the HHA to make any necessary corrections in an expeditious manner and regain compliance with the CoPs.

However, in response to the commenters' concerns, we have revised the proposed regulation in order to expand the lower range of CMP amounts in the middle category. Such added additional flexibility may permit CMS to better correlate the level of seriousness of the noncompliance with the amount of the CMP. We may 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 noncompliance. 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 have proposed both a per day and a per instance CMP at § 488.845(a). The per day CMP will 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 will impose a CMP for that instance or those individual instances of noncompliance. We have defined 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 adding 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. The total CMP amount cannot exceed $10,000 for each day of noncompliance per instance.

Comments: Commenters were opposed to per day penalties as the penalties would lead to a rapid drain on HHA capital. Other commenters were opposed to per instance CMPs. Several commenters included examples of per episode payment rates and how these payments would be insufficient to meet the financial obligations of any CMP imposed against the HHA. One commenter seemed to confuse per instance with self-reported situations of noncompliance.

Responses: Civil money penalties were designed to present an incentive to correct a deficiency in a short amount of time. As indicated previously, we have expanded the lower range of permitted per day CMP amounts to enable CMS to better correlate the seriousness of noncompliance with the amount of the CMP. The expanded lower end of the range may be particularly important if CMS imposes a CMP that begins at the lower or middle range and then increases in amount over time the longer the noncompliance remains uncorrected. In such a case, prompt remedial action by the HHA can limit the total amount of per day CMP that accrues. Per instance penalties permit us to focus on individual instances of noncompliance without having to track the duration of time the HHA remains out of compliance. As we found with SNFs and NFs, prior to establishing per instance CMPs it has largely been the case that, except where immediate jeopardy has been involved or the provider has been found to be a poor performing facility, CMPs had not been imposed where facilities have been able to correct deficiencies before a predetermined date for the completion of corrections. As a result, we believed many facilities had avoided the imposition of CMPs, that were otherwise warranted, and subsequent to achieving compliance these same facilities failed to maintain substantial compliance (otherwise known as ''yo-yo'' compliance). Thus, when the per instance CMP is selected for nursing homes, we do not envision a period to correct prior to imposition. We believe this will also be the case with HHA enforcement. What we mean by an ''instance'' in this regulation is a single deficiency identified by the tag number used as a reference on the statement of deficiencies. While we consider an instance as a singular event of noncompliance, there can be more than one instance of noncompliance identified during a survey. For example, during the course of a survey, CMS or a state may identify several instances of noncompliance, each in distinct regulatory areas. As a general matter, we anticipate imposing per instance penalties most frequently in the situation where a surveyor identifies a condition-level deficiency during the survey and the HHA took sufficient action to correct the deficiency during the time of the survey.

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

We will consider the following factors when determining a CMP amount, in addition to those factors that we will consider when choosing a type of sanction 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.

Based on the comments below, we are finalizing this section with the modifications noted below.

Comment: One commenter did not feel that size was an appropriate factor to use in determining the type of sanction. The commenter felt it discriminated against larger HHAs.

Response: The size of the HHA can significantly increase the scope of the noncompliance and impact a greater number of patients. In addition, we believe that the motivating force of the sanction may vary with the scope and resources of the HHA. Therefore we have retained size as a consideration.

Comment: One commenter felt that the availability of other agencies within a region would be used to discriminate against HHAs when there were many agencies in the area as opposed to not using the sanction when there was a shortage of HHAs.

Response: We appreciate the comment and we have removed this

factor from the list of factors to be considered.

Comment: One commenter did not think that accurate resources and data was a valid factor.

Response: We appreciate the comment. However, this information may give CMS valuable information as it relates to operations, for example, cost allocations. Therefore, we are not accepting this recommendation.

Comments: One commenter was opposed to use of the factor of the internal Quality Assessment/Performance Improvement program (QAPI).

Response: We wish to ensure that problems in HHAs are addressed promptly and that program improvements are sustained over time. Our experience with other types of providers has shown that an effectively-functioning QAPI system assists providers to restore compliance more quickly and to sustain compliance longer. Many organ transplant hospitals, for example, have a recent and exemplary history of implementing QAPI in a manner that is demonstrably saving lives. While this is not currently a specific requirement within the conditions of participation for HHAs, we believe that HHAs that have an effective QAPI program are more likely to improve the quality of their care and outcomes and to sustain those improvements over time. We wish to retain CMS discretion to accord an HHA that has implemented an effectively-functioning QAPI program with some recognition of the value in having done so on its own volition. Our experience with QAPI in other programs points to the positive association between QAPI, quality of care, and outcomes. For organ transplant programs, for example, we examined the relationship between findings of noncompliance for outcomes and findings of noncompliance in QAPI for the first 334 transplant programs surveyed under the new regulation that became effective on June 26, 2007. Of the transplant programs that were cited for having 1 year patient deaths or graft failures that exceeded the expected number, 19 percent were also cited for noncompliance with QAPI requirements, compared to only 8 percent for programs that were not cited for outcomes. In other words, organ transplant programs that did not have an effectively-functioning QAPI program were 2.4 times more likely to have patient outcomes that exceed the tolerance limits of the regulation.

By explicit inclusion of this factor in our consideration of CMPs, we recognize that QAPI promotes the same goals as alternative sanctions. Therefore, we have retained QAPI as a factor in our considerations.

Comment: Several commenters did not feel that more than one penalty should be imposed at one time.

Response: The statute does not prohibit the imposition of more than one alternative sanction and there may be instances where a combination of sanctions may be appropriate, such as the appointment of a temporary manager and a directed plan of correction.

At § 488.845(b)(2), we have provided CMS 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. We could increase a CMP in increments based upon an HHA's inability or failure 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. We may also decrease a CMP in increments to the extent that SAs find, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA is not yet in full compliance if sufficient efforts have been made to address the causes of deficiencies and sustain improvement. If an HHA resolved the immediate jeopardy situation, but not the condition-level deficiencies, we may reduce those penalties from the upper range to a lower range imposed in non-immediate jeopardy situations.

Comments: Several comments were received related to the timing of a revisit survey, which is required to determine correction of condition-level deficiencies and how it would affect the length of time a per day CMP accrues.

Response: We appreciate the comments and will develop guidance in the SOM to direct the SAs to schedule these revisits in a timely manner.

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 added 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 are establishing a three-tier system with subcategories which will establish the amount of a CMP. In § 488.845 (b)(3), (b)(4), and (b)(5), we have added the following 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.

Specifically, based on the comments and our responses below, we will impose a CMP at $10,000 per day for a deficiency or deficiencies that posed an immediate jeopardy to patients and that resulted in actual harm. For a deficiency or deficiencies that pose an immediate jeopardy situation and result in a potential for harm (but no actual harm), we will impose a CMP of $9,000 per day. For an isolated employee incident of noncompliance in violation of established HHA policy, we will impose a CMP of $8,500 per day.

- 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 $1,500 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.

Comments: As indicated previously, several commenters felt that the CMP amounts are excessive and they did not agree with the manner in which CMS structured the amount categories. Several commenters disagreed with the way CMS categorized each of the COPs within the CMP list of possible CMPs. One commenter stated that therapy service (§ 484.32) was omitted from the grid.

Response: The specified grouping of CoPs noted in the proposed rule is consistent with the groups of high risk CoPs currently used in the HHA Survey protocols. We regret the inadvertent omission of therapy services and will add this CoP to the guidance text with the grouping that includes nursing and other clinical services. Regarding the proposed ranges of CMPs, we have removed the specific sub-categories within the middle and lower ranges at § 488.845(b)(4)(i) and (ii) and § 488.845(b)(5)(i) and (ii), as we felt that this level of specificity would be more appropriate in subsequent interpretive guidance. We added instead specific amounts within the upper range to provide more guidance for imposing the CMP amount within that range. We provide that a $10,000 per day CMP will be imposed for noncompliance that is immediate jeopardy and that results in actual harm. For noncompliance that is immediate jeopardy but is not actual

harm, but is a potential for harm, we will impose $9,000 per day in CMPs. Finally, for noncompliance that is immediate jeopardy and is an isolated incident that is in violation of established HHA policies, we will impose a CMP of $8,500 per day. We will develop interpretive guidance which will provide flexibility within the ranges for the specific penalty to be imposed to better correlate the consequences with the seriousness of the noncompliance.

When we impose a CMP, we will 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 will be sent with the final amount due and the rate of interest to be charged on unpaid balances (as published in the **Federal Register**). The notice will include reference to the nature of the noncompliance; the statutory basis for the penalty; the 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 will 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 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 § 488.845(c)(2), once a notice of intent to impose the CMP had been sent to the HHA, the HHA will 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 will be offered to encourage HHAs to address deficiencies more expeditiously and to save the cost of hearings and appeals. Upon such reduction, the CMP will 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 adding at 488.845(d) that in immediate jeopardy cases, if the immediate jeopardy was not removed, the CMP will continue to accrue until we terminate the provider agreement (within 23 calendar days after the last day of the survey which first identified the immediate jeopardy). Under 488.845(d)(4), if immediate jeopardy did not exist, the CMP will continue to accrue until the HHA achieved substantial compliance or until we terminated the provider agreement. Additionally, we are adding language at § 488.845(d)(2) to specify that the per-day and per-instance CMP will 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 will 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 § 488.845(f), we have added that a CMP will 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;
- After an HHA achieves substantial compliance; or
- The HHA was terminated from the program and no appeal request was received.

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

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

Within 10 days of receipt of the notice of the imposition of a penalty, the HHA could request an IDR. Within 60 days of receipt of the notice of imposition of a penalty, the HHA could either submit a written request to waive its appeal and receive a 35 percent reduction on the final CMP amount or it 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 will 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 will be completed before any penalty was collected. However, sanctions will continue regardless of the timing of any appeals proceedings if the HHA had not met the CoPs. Requesting an appeal will not delay or end the imposition of a sanction. A CMP will 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.

Comment: Several commenters requested clarification on what day the penalty would begin to accrue.

Response: We appreciate the requests for clarification. A CMP will begin to accrue on the last day of the survey and would end on the day compliance was attained or the HHA was terminated.

(1) Offsets

To maintain consistency in recovering a CMP among other types of providers who are subject to a CMP, we are adding 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. The rate of interest assessed on any unpaid balance will be based on the Medicare interest rate published in the **Federal Register**, as specified in § 405.378(d). We will 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 will initiate action to collect the CMP through offset of monies owed or owing to the HHA. To initiate such an offset, we will 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.

We received no comments on this section of the proposed regulation and are finalizing as written.

(2) Disbursement of Recovered CMP Funds

Under 488.845(g)(1), we proposed 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 payments attributed to Medicare and Medicaid, respectively, for the FY 2007–2009 period, we proposed that 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 would be returned to the State Medicaid Agency to improve the quality of care for those who need home-based care. We also proposed that, beginning 1 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 we determine that the Medicare and Medicaid expenditure data were essentially complete.

Comments: Several comments we received indicated that they were opposed to the states sharing in the revenues from CMPs. Specifically the commenters indicated it would provide an incentive to surveyors and state agencies to impose fines so that the state agency would retain the funds for survey and certification activities.

Response: Under section 1128A(f) of the Act, collected CMP amounts are returned both to the State Medicaid Agency and to the US Treasury, as appropriate. Also, under § 1817(k)(3)(C)(ii) a portion of collected CMP funds may be used by CMS in anti-fraud functions. The amounts are disbursed in accordance with § 488.845(g). We disagree with the commenters that states would have an incentive to recommend CMP remedies in order to gain revenue. We would make the enforcement determination to impose a CMP remedy based on the survey findings. Additionally, we specifically prohibit in this rule the use of collected CMP amounts for Survey and Certification operations or the State Medicaid match.

(3) Costs of Home Health Surveys

We proposed to amend § 431.610(g)—Relations with standard-setting and survey agencies—to require that Medicaid State Plans explicitly include Medicaid's appropriate contribution to the cost of home health surveys. We proposed to add a reference to HHAs, along with NFs and ICFs/IIDs at § 431.610(g). We estimated that the appropriate national Medicaid share of total Medicare and Medicaid HHA survey costs is approximately 37 percent of the combined Medicare/Medicaid cost of surveys for dually-certified programs, based on the same cost allocation methodology we proposed to use for the disbursement to states of CMP collections, as described above. While this is a national estimate, the Medicaid share of the combined Medicare and Medicaid expense for each individual state could instead be based on the state-specific dollar amount paid by Medicaid for home health services provided by HHAs in the state compared to the combined Medicare/Medicaid total for the most recent 3-year fiscal period, prior to the year in question, for which CMS determines that the relevant data are essentially complete.

Comments: Two commenters stated that they did not think the states should share in the costs of performing surveys. One stated that these costs to the states would encourage surveyors to cite more condition-level deficiencies and not all states have voluntarily chosen to require Medicare HHA participation. One commenter stated that in many cases the states are already paying the survey costs for those agencies that are licensed but not Medicare certified.

Response: Surveys are required for determining a provider's or supplier's compliance with program participation requirements and the HHA surveys benefit both Medicare and Medicaid programs where the HHAs seek such dual certification. Thus, in accordance with OMB Circular A–87, the costs for surveys of HHAs that are certified for both Medicare and Medicaid should be shared between Medicare and Medicaid. However, to provide more time for dialogue with states and for any necessary adjustments to State Medicaid Plans, we are currently removing the proposed rule provision at § 431.610(g) in this final rule.

With regard to the concern that surveyors might be incentivized to cite more condition-level deficiencies and levy CMPs, as we have indicated previously, individual surveyors will not make the final decision as to whether a sanction may be imposed. The final decisions as to sanctions under Medicare are made by us. Finally, with regard to the comment that states are already paying the survey costs for those HHAs that are licensed, but not Medicare-certified, we appreciate that such payments are being made. We expect that states will continue to pay for the survey costs of unique state licensure requirements. Such expectations were not intended to be changed by the proposed rule.

k. Directed Plan of Correction § 488.850

We proposed in § 488.850 to include 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, we may 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 will require the HHA to take specific actions in order to bring the HHA back into compliance and correct the deficient practice(s) if the HHA failed to submit an acceptable plan of correction. As indicated in § 488.850(b)(2) an HHA's directed plan of correction will have to be developed by us or by the temporary manager, with our approval. The directed plan of correction will set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes, and the specific date the HHA will be expected to achieve such outcomes. For example, a directed plan of correction for a deficiency finding involving poor drug regimen review will 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 will be responsible for achieving compliance. If the HHA failed to achieve compliance within the timeframes specified in the directed plan of correction, we will impose one or more additional alternative sanctions until the HHA achieved compliance or was terminated from the Medicare program. Before imposing this sanction, we will provide appropriate notice to the HHA of this sanction under § 488.810(f).

Comments: One commenter felt that the development of the plan of correction should be solely the responsibility of the HHAs Board of Directors. Another commenter felt this sanction was not needed since the plan of correction was already required to be approved by the state agency.

Response: We appreciate the comments received. Imposition of this sanction will occur when, based upon the facts of the finding, a specific corrective action will be required by the SA or CMS in order for the agency to regain compliance. The SA or CMS may also impose this sanction when the HHA fails to submit an acceptable plan of correction.

l. Directed In-Service Training § 488.855

We proposed in § 488.855 the requirements for conducting directed in-service training for HHAs with deficiencies. We have found that compliance problems are frequently a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and best practices for favorable patient outcomes, such as advances in infection control and reducing pressure ulcers. In § 488.855(a) directed in-service training would be imposed where staff performance resulted in noncompliance and it is determined that 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 could be imposed alone or in addition to other alternative sanctions.

At § 488.855(a)(3), HHAs will 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 will 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 will only recommend possible training locations to an HHA and not require that the HHA utilize a specific school/center/provider. The HHA itself will pay for the directed in-service training for its staff. The ultimate evaluation of the usefulness 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 § 488.855(b), if the HHA did not achieve compliance after such training, we could impose one or more additional sanctions.

Comments: One commenter objected to this sanction on the grounds that it felt the RNs at their agency were already educated at the BS level and that the expense of the sanction to require consultation from the university level would be prohibitive.

Response: We appreciate the comment and feel the commenter may have misunderstood the context of the proposed language. Directed in-service will need to be at a high level of expertise, not necessarily at the university level. We included this requirement to require additional professional support/training for current HHA staff. Since the usefulness of the training will be demonstrated by the improved competency of the HHA staff, we encourage the HHA to find and evaluate the directed-in service programs that will best suit the HHA's needs.

Comment: One commenter feels that CMS should have a greater level of commitment to provide training on CoPs with the industry.

Response: We make every effort to include the HHA industry in their educational efforts. When webinars are utilized for surveyor training, these webinars are available to the industry for their use. Nonetheless, we appreciate the comment and will consider additional means to reach out to HHAs.

m. Continuation of Payments to HHAs With Deficiencies § 488.860

We proposed in § 488.860 provisions 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 of 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, and
- 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 plan has been approved; 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 proposed these three criteria in § 488.860(a). If any of these three requirements set forth in the Act and in our final rule are not met, an HHA with condition-level deficiencies will not receive any federal payments from the time that deficiencies were initially identified. We will also terminate the agreement before the end of the 6-month correction period, which begins on the last day of the survey, in accordance with § 488.865 if the requirements at § 488.860(a)(1) are not met. If any sanctions are also imposed, they will stop accruing or end when the HHA achieves compliance with all requirements, or when the HHA's provider agreement is terminated, whichever is earlier.

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 have proposed in § 488.830(d) that we will terminate the provider agreement.

Comments: One commenter wanted greater clarification of this section. They indicated that this sanction seemed to make the imposition of alternative sanctions mandatory, unless the HHA meets the criteria set forth in this section.

Response: Alternative sanctions are not mandatory, but may be imposed if we believe it is a more appropriate action to prompt and to bring the HHA into compliance. The significant benefit of most alternative sanctions is that payment may continue to the HHA while the sanction is in place. Without the choice of alternative sanctions, the HHA is subject only to termination, either within 90 days or immediately in the case of immediate jeopardy. Section 1891(e)(4)(c) of the Act provides that if alternative sanctions are imposed, and the HHA submits an acceptable plan of correction, then the HHA agrees to repay the payments received if the HHA ultimately fails to take corrective action

in accordance with the approved plan of correction and its established timetables.

n. Termination of Provider Agreement (§ 488.865)

We proposed in § 488.865(a), to 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 § 488.860. Termination will also end any alternative sanctions imposed against the HHA, regardless of any proposed timeframes for the sanction(s) originally specified. In § 488.865(b) we will terminate the provider agreement if (1) the HHA failed to correct condition-level deficiencies (that are not immediate jeopardy) within 6 months if the HHA is not in compliance with the conditions of participation; (2) the HHA failed to submit an acceptable plan of correction for approval by us under § 488.810; (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 § 488.860. If CMS or the SA determined deficiencies existed which posed immediate jeopardy to patient health and safety, we will terminate the provider agreement in accordance with § 488.825. The provider could also voluntarily terminate its agreement. CMS and the SA will, 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 continuing 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 added that the HHA could appeal the termination of its provider agreement in accordance with 42 CFR part 498.

Comments: Several commenters alleged that CMS would not be affording due process to the HHA with the implementation of sanctions, including CMPs, before the HHA has been allowed full access to appeal and the appeal is resolved. One commenter stated that the HHA should be made ''whole'' in the event that the HHA prevails in the appeal.

Response: We disagree that the HHA is denied due process because the sanctions are applied prior to the completion of the appeals process, primarily because we believe the intent of the Act is to impose remedies as soon as possible in order to protect the patients. We believe that post-sanction hearings are entirely compatible with due process. Courts that have addressed this issue have concluded that, because the provider has numerous opportunities to prevent mistakes from occurring and to present its side of the story both during the survey process, at the exit interview, and by submitting written statements and a plan of correction, due process is satisfied by the availability of post-sanction hearings. See, for example, *Caton Ridge Nursing Home* v. *Califano,* 596 F.2d 608 (4th Cir. 1979), *Green* v. *Cashman,* 605 F.2d 945 (6th Cir. 1979), *Northlake Community Hospital* v. *United States,* 654 F.2d 1234 (7th Cir. 1981), Geriatrics, Inc. v. Harris, 640 F.2d 262 (10th Cir. 1981), cert. denied454 U.S. 832, 102 S.Ct. 1295, *Americana Healthcare Corp.* v. *Schweiker,* 688 F.2d 1072, 1082–83 (7th Cir. 1982), *cert. denied,* 459 U.S. 1201 (1983), *Cathedral Rock of North College Hill, Inc.* v. *Shalala,* 223 F.3d 354, 364–65 (6th Cir. 2000). Although the Supreme Court has not directly decided the issue of due process requirements when a provider is terminated, the Court has decided in *O'Bannon* v. *Town Court,* 447 U.S. 773, 100 S.Ct. 2467 (1980), that nursing home residents are not entitled to a pre-termination hearing. The Court reached this result notwithstanding the fact that residents were the intended beneficiaries of the provider agreement through their entitlement to high quality care. Moreover, consistent with the balancing of interests formula first enunciated by the Supreme Court in *Mathews* v. *Eldridge,* 434 U.S. 319 (1976), we have concluded, first and foremost, that the private interest that HHAs have in their continued participation in the Medicare and Medicaid programs must give way to the Government's interest in protecting the health and safety of the patient population. Additionally, in light of the opportunities available to providers to question the accuracy of survey findings at various points during the survey process (including during the survey, exit conference, and through informal meetings with state or federal officials), we believe that the chances for an erroneous deprivation are quite small when compared to the enormous delay in the correction of noncompliance that could occur were hearings to be routinely held prior to the institution of remedies. The use of an informal dispute resolution process, as we discussed earlier in this preamble, should serve to reduce even further the chances of an erroneous deprivation.

The statutory provisions clearly reflect the desire expressed in the enactment's legislative history that remedies be applied swiftly once deficiencies are identified. Specifically, section 1891(f)(3) of the Act requires that the Secretary develop criteria detailing the manner in which remedies are to be imposed and that they be designed so as to minimize the time between the identification of violations and final imposition of the remedies. We believe it would be incompatible with these pronouncements were we to devise an appeal scheme that would provide for hearings before the imposition of remedies. Moreover, we conclude that this is the case regardless of whether the HHA's deficiencies pose immediate jeopardy to resident health or safety since the Act makes no distinction on this basis and because the delay in imposing remedies once noncompliance has been identified could be considerable.

Although not required by law, we also added a provision for Informal Dispute Resolution so as to offer an additional safeguard that enables the HHA to provide information to dispute any condition-level finding that prompts a sanction. We are also adding an exception to the general notice provision and amending § 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 we give notice to any provider and the public at least 15 days before the effective date of a termination of a provider agreement. We added a new clause in § 489.53(d)(2)(iii) which will provide for a timing exception to this general notice rule. Specifically, we added that for HHA terminations based on deficiencies that posed immediate jeopardy to patient health and safety, we will 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 will give concurrent notice to the public when such termination occurred.

Comment: One commenter wanted assurance of a smooth transition of patients if an HHA is terminated.

Response: It is current CMS policy for the SA and CMS Regional Office, if applicable, to assist with the safe and timely transfer of HHA patients in the event of HHA termination. Current policy requires SA and the CMS

Regional Offices to assist with the safe transition of patients to new HHAs, if needed.

C. Provider Agreements and Supplier Approval

We are amending § 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 regulation at § 488.740 concerning appeals.

We did not receive any comments in response to our proposals in this section. Therefore, we are finalizing these provisions as proposed.

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 have solicited comments related to additional public notices. We considered 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 also solicited comments on the definition of a ''per instance'' of noncompliance when imposing a CMP sanction.

Comments: We received many comments opposed to any public notice other than for termination. Several commenters thought that public notice would be posted on Home Care Compare. Several comments indicated that a public notice would damage an agency's reputation.

Response: We appreciate the comments received and want to clarify that by public notice we meant a notice published in the local newspaper, similar to the notices published for termination. We agree with these comments and we will not include in the regulation a requirement for public notice when alternative sanctions are imposed.

VI. Collection of Information Requirements

While this final rule contains information collection requirements, this rule does not revise any of the information collection requirements or burden estimates 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 final rule revise any of the information collection requirements or burden estimates pertaining 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 § 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 at the 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.

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 codifies some existing CMS policies and establishes new requirements that are consistent with OBRA '87 mandates as discussed in the Background and Statutory Authority sections of this preamble. State Surveyor recordkeeping requirements already exist in Forms CMS–1515 and CMS–1572 (OCN 0938–0355) and in CMS–2567 (OCN 0938–0391). 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, when necessary.

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, with minimal state expense. 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 OCN 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

In section IV of the preamble, we note that section 3004 of the Affordable Care Act amends 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) was approved by OMB on September 28, 2012, under OCN 0938–1153. Technically, the form is not associated with this rule but is discussed within the preamble to provide background information.

VII. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (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 final rule does not reach the economic threshold and thus is not considered a major rule. We are not required to prepare an analysis for the RFA. However, as a courtesy we are providing the public with the impact analysis. 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 final 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 of the payment amount otherwise made under section 1895 of the Act.

C. Overall Impact

The update set forth in this final 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 provisions in this rule is approximately $10 million in CY 2013 savings. The -$10 million impact reflects the distributional effects of an updated wage index ($70 million decrease), the 1.3 percent HH payment update ($260 million increase), the revised FDL ratio ($50 million increase), and the 1.32 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($250 million decrease). The $10 million in savings is reflected in the first row of column 3 of Table 28 as a 0.01 percent decrease in expenditures when comparing the current CY 2012 HH PPS to the 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 rule will not have a significant economic impact on a substantial number of small entities. We define small HHAs as either non-proprietary or proprietary with total revenues of $13.5 million or less in any 1 year. We estimate that approximately 25 percent of HHAs are classified as non-proprietary. Analysis of Medicare claims data reveals a 0.05 percent decrease in estimated payments to small HHAs in CY 2013.

A discussion on the alternatives considered is presented in section VII.E. below. The following analysis, with the rest of the preamble, constitutes our RFA analysis.

In this final rule, we stated that our analysis shows 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 more than larger HHAs by the 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 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule applies to HHAs. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on the operations of small rural hospitals.

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

D. Detailed Economic Analysis

This final rule sets forth updates to the HH PPS rates contained in the CY 2012 HH PPS final rule. The impact analysis of this final rule presents the estimated expenditure effects of policy changes finalized 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.

Table 28 represents how HHA revenues are likely to be affected by the policy changes finalized 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 28 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 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 0.37 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 0.01 percent.

As shown in Table 28, 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 will be impacted positively as a result of the provisions in this rule. In addition, free-standing, other volunteer/non-profit agencies and facility-based volunteer/non-profit agencies in urban areas will be impacted positively.

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TABLE 28: Home Health Agency Policy Impacts for CY 2013, by Facility Type and Area of the Country

Group	Comparisons	Impact of all CY 2013 Policies[1]
	Percent change due to the effects of the updated wage index	
All Agencies	-0.37%	-0.01%
Type of Facility		
Free-Standing/Other Vol/NP	0.02%	0.61%
Free-Standing/Other Proprietary	-0.50%	-0.21%
Free-Standing/Other Government	-0.43%	0.07%
Facility-Based Vol/NP	-0.04%	0.43%
Facility-Based Proprietary	-0.47%	-0.08%
Facility-Based Government	-0.40%	0.01%
Subtotal: Freestanding	-0.40%	-0.05%
Subtotal: Facility-based	-0.11%	0.35%
Subtotal: Vol/NP	0.00%	0.55%
Subtotal: Proprietary	-0.50%	-0.21%
Subtotal: Government	-0.42%	0.04%
Type of Facility (Rural * Only)		
Free-Standing/Other Vol/NP	-0.70%	-0.28%
Free-Standing/Other Proprietary	-0.90%	-0.63%
Free-Standing/Other Government	-0.53%	0.07%
Facility-Based Vol/NP	-0.53%	-0.07%
Facility-Based Proprietary	0.08%	0.49%
Facility-Based Government	-0.55%	-0.08%
Type of Facility (Urban * Only)		
Free-Standing/Other Vol/NP	0.14%	0.76%
Free-Standing/Other Proprietary	-0.44%	-0.15%
Free-Standing/Other Government	-0.30%	0.07%
Facility-Based Vol/NP	0.10%	0.58%
Facility-Based Proprietary	-0.72%	-0.34%
Facility-Based Government	-0.21%	0.14%
Type of Facility (Urban* or Rural*)		
Rural	-0.78%	-0.43%
Urban	-0.29%	0.07%
Facility Location: Region*		
North	0.13%	0.86%
South	-0.78%	-0.48%
Midwest	-0.25%	0.01%
West	0.56%	0.92%
Outlying	-0.50%	-0.13%
Facility Location: Area of the Country		
New England	0.55%	1.24%
Mid Atlantic	-0.12%	0.64%
South Atlantic	-0.41%	-0.09%

Group	Comparisons	Impact of all CY 2013 Policies[1]
	Percent change due to the effects of the updated wage index	
East South Central	-1.25%	-1.10%
West South Central	-0.93%	-0.59%
East North Central	-0.30%	-0.06%
West North Central	-0.02%	0.34%
Mountain	-0.69%	-0.24%
Pacific	1.12%	1.43%
Outlying	-0.50%	-0.13%
Facility Size: (Number of First Episodes)		
< 100	-0.57%	-0.25%
100 to 249	-0.58%	-0.26%
250 to 499	-0.49%	-0.15%
500 to 999	-0.39%	-0.07%
1,000 or More	-0.11%	0.32%
Facility Size: (estimated total revenue)		
Small (estimated total revenue <= $13.5 million)	-0.38%	-0.05%
Large (estimated total revenue > $13.5 million)	-0.19%	0.64%

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, revised FDL ratio, the 1.3 percent payment update and the 1.32 percent case-mix adjustment.

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E. Alternatives Considered

In implementing the case-mix adjustment for CY 2013, along with the home health payment update and the updated wage index, the aggregate impact will be a net decrease of $10 million in payments to HHAs, resulting from a $70 million decrease due to the updated wage index, a $260 million increase due to the home health payment update, a $50 million increase due to the revised FDL ratio, and a $250 million decrease from the 1.32 percent case-mix adjustment. In the proposed rule, we considered not implementing the 1.32 percent case-mix adjustment. However, 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. In the proposed rule, we stated that we believed 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 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 are finalizing a 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 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).

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 regulation will 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 was approximately 2.2 percent of the HHAs (small entities affected) which is less than 5 percent of total HHAs surveyed.

We believe the benefit will be in assuring public health and safety. We believe this final 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 29: CMS Survey Data CY 2010

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 final regulation.

Because implementation of the complex and far-reaching provisions of this final rule for CMS will 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 provide for staggered effective dates of July 1, 2013 for the provisions of part 488, subparts I and J and parts 489 and 498 of the rule and July 1, 2014 for § 488.745, § 488.840 and § 488.845.

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 604 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 final regulation will

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 final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We will 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 will 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 will 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 $410,972 in annual operating costs. The provisions in this final 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.

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 30, we have prepared an accounting statement showing the classification of the transfers associated with the provisions of this final 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 final rule.

TABLE 30: Accounting Statement

Classification of Estimated Transfers, from the CY 2012 HH PPS to the CY 2013 HH PPS	
Category	**Transfers**
Annualized Monetized Transfers	-$10 million
From Whom to Whom?	Federal Government to HH providers.

H. Conclusion

In conclusion, we estimate that the net impact of the proposals finalized in this rule is approximately $10 million in CY 2013 savings. The $10 million impact to the CY 2013 HH PPS reflects the distributional effects of an updated wage index ($70 million decrease), the 1.3 percent home health payment update ($260 million increase), a new FDL ratio of 0.45 ($50 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.

VIII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

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 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 amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 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. In instances where the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra unnecessary visit or delaying a visit, then it is acceptable for the qualified therapist from that discipline to provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 14th Medicare-covered therapy visit, but no later than the 13th Medicare-covered therapy visit.

(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 schedule to occur after the 16th therapy visit but no later than the 19th therapy visit per the plan of care. In instances where the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra, unnecessary visit or delaying a visit, then it is acceptable for the qualified therapist from that discipline to provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 20th Medicare-covered therapy visit, but no later than the 19th Medicare-covered therapy visit.

(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), (B), (C), and (D) as paragraphs (a)(1)(v)(C), (D), (E), and (F), respectively.
■ C. Adding new paragraphs (a)(1)(v)(A) and (B).
■ D. Revising newly redesignated paragraphs (a)(1)(v)(C) and (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 a physician who cared for the patient in an acute or post-acute care facility or by a nonphysician practitioner in collaboration with or under the supervision of such an acute or post-acute care physician and that nonphysician practitioner is not directly communicating to the certifying physician the clinical findings (that is, 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 nonphysician 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) respectively. The documentation must be clearly titled and dated and the

documentation must be signed by the certifying physician.

* * * * *

PART 484—HOME HEALTH SERVICES

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

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

■ 6. 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

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

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

■ 8. 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.

* * * * *

■ 9. 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.

* * * * *

■ 10. 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.

■ 11. 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.

* * * * *

■ 12. Subpart I is added to read as follows:

Subpart I—Survey and Certification of Home Health Agencies

Sec.

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 fewer specific standards or 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 additional conditions of participation not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is 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 identified on a standard survey, including deficiencies which could result in actual or potential harm to patients of 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 one or more or all additional conditions of participation not examined during the standard survey.

(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 was out of compliance with a condition of participation.

§ 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, or knowledge 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 of this part.

§ 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, must include the specific deficiencies that are disputed, and must be made within the same 10 calendar day period that the HHA has for submitting an acceptable plan of correction.

■ 13. Subpart J is added to read as follows:

Subpart J—Alternative Sanctions for Home Health Agencies With Deficiencies

Sec.

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 the final determination of 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.

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 condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency citation cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator based upon qualifications described in §§ 484.4 and 484.14(c) of this chapter. The HHA's governing body must ensure that the temporary manager 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 one or more conditions of participation found through a survey 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.

(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.

(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 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 deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, have a condition-level deficiency or deficiencies that do not pose immediate jeopardy, or because the HHA has repeat noncompliance that results in a condition-level deficiency based on the HHA's failure to correct and sustain compliance, CMS will:

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

(2) Impose one or more alternative sanctions set forth in § 488.820(a) through (f) of this part as an alternative to termination, for a period not to exceed 6 months.

(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) of this part.

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

(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 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 noncompliance 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, CMS initiates termination of the provider agreement and may impose additional sanctions.

(4) Temporary management will not exceed a period of 6 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.

§ 488.840 Suspension of payment for all new patient admissions.

(a) *Application.* (1) CMS may suspend payment for all new admissions 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, CMS provides the HHA notice of the suspension of payment for all new admissions as set forth in § 488.810(f). The CMS notice of suspension will include the nature of the noncompliance; 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 sanction may be imposed anytime an HHA is found to be out of substantial compliance.

(ii) Suspension of payment for patients with new admissions 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) 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.

(iv) 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 failure 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.

(i) $10,000 per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) $9,000 per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) $8,500 per day for an isolated incident of noncompliance in violation of established HHA policy.

(4) *Middle range of penalty.* Penalties in the range of $1,500–$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.

(5) *Lower range of penalty.* Penalties in this range of $500–$4,000 are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

(6) *Per instance penalty.* Penalty 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 subsection, the civil money penalty is not reduced by 35 percent.

(d) *Accrual and duration of penalty.* (1)(i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the HHA was out of compliance, as determined by CMS.

(ii) 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.

(2) 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 day 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 payments 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.

§ 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

■ 14. The authority citation continues to read as follows:

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

■ 15. 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

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

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

■ 17. 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 paragraph (d)(12) of this section for SNFs, NFs, and HHAs the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406 or § 488.740 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: October 24, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 25, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–26904 Filed 11–7–12; 8:45 am]

BILLING CODE 4120–01–P