FINAL RULE: MEDICARE PROGRAM; HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CY 2013
SUMMARY

November 16, 2012

On November 2, 2012, the Centers for Medicare & Medicaid Services (CMS) made public a final rule for the CY 2013 update to the Medicare home health prospective payment system (HH PPS) (CMS-1358-F). The rule appeared in the November 8, 2012 *Federal Register* (77 FR 67068-67170). Included is an update to the market basket, case-mix adjustments due to variation in costs among different units of services, an adjustment for case-mix up-coding, adjustments for geographic differences in wage levels, outlier payments, submission of quality data and additional payments for services provided in rural areas. CMS also finalizes new hospice quality reporting program requirements.

In addition, the rule finalizes requirements for unannounced, standard, and extended surveys of home health agencies (HHAs) and provides a number of alternative (i.e., intermediate) sanctions if HHAs are out of compliance with Federal requirements. CMS expects to use monetary penalties and payment suspensions more sparingly than under the proposed rule and has modified the range of potential penalties. CMS will not use civil monetary penalties, payment suspensions and the informal dispute resolution process until July 1, 2014 (and not one year after issuance of the rule, as was proposed). Most other provisions of the final rule are effective January 1, 2013.

The final CY 2013 national standardized 60-day episode payment rate for episodes beginning and ending in CY 2013 when such services are provided in an urban area is $2,137.73 (for those home health agencies (HHAs) that submit the required quality measures). The comparable final rate is $2,201.86 when home health services are provided in a rural area.[1]

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[1] Under the Affordable Care Act (ACA), there is a 3 percentage point add-on to the urban national standardized 60-day payment rate for home health services provided in a rural area starting on or after April 1, 2010 through December 31, 2015.

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I. Impact[2]

CMS estimates that the overall impact of the final rule on HHAs will be a decrease of about 0.01% for a total of $10 million in Medicare savings for CY 2013. The -$10 million impact reflects the distributional effects of an updated wage index ($70 million decrease), the 1.3% HH payment update ($260 million increase), the revised fixed dollar loss (FDL) ratio ($50 million increase), and the 1.32% case mix adjustment applicable to the national standardized 60-day episode rates ($250 million decrease). The overall .01% reduction for all HHAs, however, varies by type and location of HHAs as highlighted in Table 28 (77 FR 67159). As CMS observes, in general, facility-based, proprietary agencies in rural areas will be positively affected as a result of the provisions of this rule. In addition, free-standing, other volunteer-non-profit agencies and facility-based volunteer/non-profit agencies in urban areas will experience a positive impact. The following provides some of the information from the summary impact table.

Home Health Agency Policy Impact for CY 2013, by Facility Type and Area of the Country	
Group	**Impact of all CY 2013 Policies**
All Home Health Agencies	-0.01%
Non-profit HHAs	
Free-Standing	+0.61%
Facility-Based	+0.43%
Proprietary HHAs	
Free-Standing	-0.21%
Facility-Based	-0.08%
Government-owned HHAs	
Free-Standing	+.07%

[2] This is from the "Regulatory Impact Analysis" section of the final rule and is discussed in greater detail later in this summary.

Home Health Agency Policy Impact for CY 2013, by Facility Type and Area of the Country	
Group	**Impact of all CY 2013 Policies**
Facility-Based	+0.01%
Urban HHAs	+0.07%
Rural HHAs	-0.43%
Table 28, Home Health Agency Policy Impacts for CY 2013, By facility Type and Area of the Country, 77 FR 67159-67160	

II. Provisions of the Final Rule

A. Case Mix Measurement

For the CY 2013 proposed rule, CMS updated its estimates of real and nominal case-mix growth using 2010 data (except for the living arrangement variables which were predicted based on trends from 2007-2009). CMS estimated that 15.97% of the total percentage change in the national average case-mix weight since the interim payment system baseline through 2010 was due to changes in real case-mix. When taking into account the total measure of case-mix change and the 15.97% of total case-mix change estimated as real from 2000 to 2010, CMS obtained a final nominal case-mix change measure of 20.08% from 2000 to 2010. To fully account for the remainder of the 20.08% increase in nominal case-mix beyond that which was accounted for in previous payment reductions, the percentage reduction to the national standardized 60-day episode rates for nominal case-mix change would be 2.18%. CMS considered proposing a 2.18% reduction to account for the remaining increase in measured nominal case-mix, and sought comments on that proposal, rather than moving forward with the 1.32% reduction promulgated in the CY 2012 HH PPS final rule. CMS nonetheless proposed for CY 2013 to move forward with the 1.32% payment reduction to the national standardized 60-day episode rates as promulgated in the CY 2012 HH PPS Final Rule (76 FR 68532).

CMS advises 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 [CMS] continues to address the issue of the increase in nominal case-mix in future rulemaking."

Commenters urged that CMS not implement across-the-board payment reductions in response to coding intensity increases but rather be more targeted on those agencies that are found to be gaming the system by up-coding, on specific coding practices that have caused nominal case-mix increases, or on agencies with above average margins. In response, CMS says that it understands that nominal coding changes have resulted from a number of factors, not necessarily gaming, but that there still remains a need to exclude nominal case-mix effects that are unrelated to changes in patient severity. CMS further responds that the research by Dr. David Grabowski and his

Harvard University team support the agency's reasons for not proposing targeted reductions.[3] CMS further advises that it continues to explore potential changes to the HH PPS which could deter future nominal case-mix growth. An example is the recalibration implemented in the CY 2012 final rule, and possible changes in conjunction with rebasing.

CMS also identifies specific measures that the government has launched to identify fraudulent and abusive activities that contribute to up-coding. CMS refutes the claim by some commenters that patients with more serious medical conditions are now being treated by home health agencies by referencing CMS' own analysis of patients' conditions, the sources of home health patients treated by home health agencies (e.g., admitted from the hospital, SNF or the community), prior hospital lengths of stay, and other possible factors that might increase the severity of the home health patient population.

In addition, CMS addresses other concerns raised by commenters about how the across the board 1.32% reduction would be too blunt a policy because it would have particularly adverse effects on home health agencies with certain characteristics (e.g., those operating with margins that are less than zero; hospital-based home health care; access for higher-cost patients, quality improvement investments, etc.). CMS describes its own analyses of margin and other data and concludes that HH payments are adequate and that the payment changes' impact would be minimal, with an average effect on payments of -0.01%. CMS will continue to monitor for unintended consequences of the payment reductions on access to home health services for beneficiaries and also use Open Door Forums and other venues "to solicit information from agencies on any actual access issues they witness." (CMS notes that the study mandated by the Affordable Care Act (ACA) 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, is projected to be available in 2014.)

CMS also addresses a number of specific critiques by commenters of the data and model that it uses to determine coding intensity as well as responds to some comments advocating for the full case-mix adjustment of 2.18% that would account for the nominal case-mix growth through 2010. CMS says that because of several factors, such as the CY 2012 recalibration, it is taking the more conservative path of applying the 1.32% reduction."

CMS adopts as final its proposed 1.32% payment reduction for CY 2013 to the national standardized 60-day episode rates. CMS says that this "reduction enables us to account for nominal case-mix growth which we have identified through CY2009 and to collect additional data on case-mix change, such as data on the effects of the 2012 recalibration of the HHS PPS case-mix weights."

[3] The Harvard analysis is available at: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HHPPS_HHAcasemixgrowthFinalReport.pdf

B. Outlier Policy

Background and Statutory Update

CMS repeats in the final rule's preamble the background and statutory update on the outlier payment policy. Prior to the enactment of the ACA, outlier payments could not exceed 5% of actual or estimated total home health payments in a given year. Under the ACA, the Secretary may provide for an addition or adjustment of up to 2.5% of total projected HH payments to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care.

Beginning in CY 2011, the CMS outlier policy reduces payment rates by 5% and targets up to 2.5% of total estimated HH PPS payments to be paid as outliers. To do this for CY 2012, CMS first returned the 2.5% held for the target CY 2010 outlier pool to the national standardized 60-day episode rates, the national per visit rates, the Low Utilization Payment Amount (LUPA) add-on payment amount, and the Non-Routine Supplies (NRS) conversion factor for CY 2010. CMS then reduced the rates by 5%. For CY 2011 and subsequent calendar years, CMS targets up to 2.5% of estimated total payments to be paid as outlier payments, and applies a 10% agency-level outlier cap.

Loss-Sharing Ratio and Fixed Dollar Loss (FDL) Ratio. CMS again explains in the final rule's preamble that for a given level of outlier payments, there is a trade-off between the values selected for the Fixed Dollar Loss (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 statutory 2.5% aggregate level. In the past, CMS has used a value of 0.80 for the loss-sharing ratio, which CMS says is relatively high, but preserves incentives for HHAs to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80% 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% of total HH PPS payments, CMS implemented an FDL ratio of 0.67, and 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% of the additional estimated costs.

In the CY 2013 HH PPS proposed rule issued in the July 13, 2012 **Federal Register** (77 FR 41548), CMS described its methodology for updating the FDL but did not propose to change it, in part, because it had not been able to verify these projections in its paid claims files since the 10% agency-level cap on outlier payments had been implemented on January 1, 2010. Another factor was the "the implementation in the CY 2012 HH PPS final rule of changes to the case-mix

weights, which put more weight on non-therapy cases that typically are more likely to receive outlier payments. The data showing the effects of the changes to the case-mix weights on outlier payments will not be available for analysis until next year." CMS describes data errors that have resulted in inaccuracies in outlier payment amounts in its paid claims files for CY 2010 and 2011. CMS concludes its discussion of the loss-sharing ratio and the FDL ratio by noting that "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." CMS finalizes an FDL ratio of 0.45% in order to pay up to, but no more than, 2.5% of total HH PPS payments as outlier payments. (See the next section for additional discussion.)

Outlier relationship to the HH Payment Study. In the proposed rule, CMS advised that the study mandated by the ACA on HH payment revisions to ensure access to care and payment for HH patients with high severity of illness, due no later than March 1, 2014, may include analysis of potential revisions to outlier payments to better reflect costs of treating such Medicare beneficiaries. (Note that in the final rule's preamble, CMS says that the study is projected to be available in 2014 but does not say by March 1st.)

Comments included: a request that CMS exempt special-needs HHAs that serve high-cost patients with multiple clinical issues from the 10% outlier cap or that CMS otherwise develop a remedy to the limitations in the current policy in addressing high cost cases; that CMS recalculate outlier payment levels for 2011 and 2012 now that claims processing errors have been corrected; and that CMS consider revising the 2013 FDL ratio in the event that total outlier spending is less than 2.5%. In response, CMS references the statutory limits on its authority (it cannot change the 2.5% outlier pool, the 5% reduction to the HH PPS payment rates to fund the pool or the 10% outlier cap. CMS intends to analyze alternatives to the current policy as part of the ACA required home health study.

CMS advises that it was able to correct the claims processing errors that resulted in inaccuracies in outlier payment amounts in its 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% of total HH PPS payments. In order to pay up to, but no more than 2.5% of total HH PPS payments as outlier payments, the FDL ratio would need to be revised to 0.45 for CY 2013. As a result, CMS is finalizing an FDL ratio of 0.45% in order to pay up to, but no more than 2.5% of total HH PPS payments as outlier payments. CMS believes that the 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

Section 1895(b)(3)(B) of the Social Security Act (SSA) 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. CMS

describes the development of an HHA input price index or "market basket" and notes that the percentage change in the HH 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.

CMS last rebased the home health market basket effective with the CY 2008 update, using CY 2003 data. CMS proposed to both rebase and revise the home health market basket for CY 2013 using CY 2010 Medicare cost report (MCR) data.[4] (See 77 FR 67081-67090 for CMS's discussion of its methodology. Note that some of the final rule tables show different values in some cells from those in the proposed rule reflecting updated information.)

Comments on the proposed rebasing as well as on the market basket updates reflected concerns about the frequency of rebasing, the nature and timing of the underlying data, and various aspects of the methodology for calculating labor costs.

In the final rule, table 10 (77 FR 67090) 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%, while the forecasted rate of growth for the current 2003-based home health market basket is 2.1%. CMS explains that 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 Employment Cost Indexes (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.

In the 2003-based HH market basket, the labor-related share was 77.082% while the remaining non-labor-related share was 22.918%. In the revised and rebased market basket, the labor-related share is 78.535%. (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%. 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.

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 NonLabor-Related	22.918	21.465
Table 11, 77 FR 67090		

[4] CMS explains that "rebasing" and "revising," while often used interchangeably, denote different activities. The term "rebasing" means moving the base year for the structure of costs of an input price index (in this case, 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.

CY 2013 Market Basket Update for HHAs. For CY 2013, CMS proposed to use an estimate of the proposed 2010-based HHA market basket to update payments to HHAs based on the best available data, which historically has been based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's second quarter 2012 forecast with history through the first quarter of 2012, the projected HHA market basket update for CY 2013 was 2.5%.

Consistent with the agency's historical practice of estimating market basket increases based on the best available data, CMS's final rule provides for a 2.3% market basket update for CY 2013. This reflects IGI's third quarter 2012 forecast with history through the 2nd quarter 2012.

2. CY 2013 Home Health Payment Update Percentage

Under section 3401(e) of the ACA, the Secretary is required to reduce the HH market basket percentage for each of 2011, 2012, and 2013, by 1 percentage point. This may result in the market basket percentage increase being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

CMS had proposed that the CY 2013 market basket update of 2.5%, reduced by 1 percentage point, would result in a CY 2013 home health payment update of 1.5%. In the final rule, the CY 2013 market basket update of 2.3%, reduced by 1 percentage point, results in a 1.3% update.

3. Home Health Quality Reporting Program (QRP)

Home health agencies that meet quality data reporting requirements are eligible under the law for the full HH market basket percentage increase. HHAs that fail to meet these requirements are subject to a 2 percentage point reduction to the HH market basket percentage increase. The law also directs the Secretary to establish procedures for making quality data available to the public, ensuring though that the HHA has the opportunity to review the data prior to publication.

Under CMS rules, the quality reporting requirements can be met by the submission of OASIS assessments and Home Health Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS). In the CY 2012 HH PPS final rule (76 FR 68576), CMS 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), CMS finalized that it would also use measures derived from Medicare claims data to measure home health quality.

Requirements for CY 2014 payment and subsequent years

(1) Submission of OASIS data. For CY 2013, CMS proposed to consider OASIS assessments submitted by HHAs to CMS 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 would

allow for 12 full months of data collection and give CMS time to analyze and make any necessary payment adjustments to the payment rates for CY 2013. CMS proposed to continue this pattern for each subsequent year beyond CY 2013, considering OASIS assessments submitted in the time frame between July 1 of the calendar year two years prior to the calendar year of the Annual Payment Update (APU) effective date and July 1 of the calendar year one year prior to the calendar year of the APU effective date as fulfilling the OASIS portion of the quality reporting requirement for the subsequent APU.

CMS received only one comment which was supportive of its policy. This provision of the proposed rule is adopted as final without modification.

(2) Acute Care Hospitalization Claims-Based Measure. CMS believes that claims data are a more robust source of data for accurately measuring acute care hospitalizations than other data sources. Accordingly, CMS proposed that the claims-based Acute Care Hospitalization measure replace the OASIS-based measure on Home Health Compare. The OASIS-based measure, however, would continue to be reported on the agency-specific Certification and Survey Provider Enhanced Reporting system (CASPER) reports. CMS had advised in the proposed rule though that because of technical issues with Home Health Compare files, the reporting of both "Emergency Department Use Without Hospitalization" and "Acute Care Hospitalization" would be delayed until the technical issues were resolved. The OASIS-based Acute Care Hospitalization measure would continue to be made available to the public via Home Health Compare until it was replaced with the claims-based measure.

Commenters were mostly supportive of the proposal and the use of claims-based measures in general although some questioned specific aspects of CMS's approach.

CMS advises in the final rule that it has resolved the technical challenges noted in the proposed rule and in August, the CASPER reports included Acute Care Hospitalization and Emergency Department Use Without Hospitalization measure rates that CMS calculated using claims data. CMS says that the claims-based measure rates for these measures will be publicly reported on Home Health Compare. Further, CMS clarifies that when it referred to the Acute Care Hospitalization and Emergency Department Use Without Hospitalization measures as "replacing" the OASIS-based measures, the intended message was that the measures will be calculated using a new source of data. The measure concept has not changed.[5] Additional information is provided to assist HHAs understand the measures, and CMS notes that it is considering whether to begin calculating other OASIS-C outcome measures using claims data as well as considering the feasibility of proposing to adopt readmission measures, which might include a 30-day measure of re-hospitalization that would apply to home health patients who

[5] 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 have been available since September 12 on the CMS Home Health Quality Initiative web page at www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

begin home health immediately after an inpatient hospital stay. This measure would be similar to the "Hospital-Wide All-Cause Unplanned Readmission" measure recently adopted for the Hospital Inpatient Quality Reporting Program.

Home Health Care CAHPS Survey (HHCAHPS). In the proposed rule, CMS noted that in the CY 2012 HH PPS final rule (76 FR 68577), it 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, CMS moved forward with the HHCAHPS linkage to the pay-for-reporting requirements affecting the HH PPS rate update for CY 2012. CMS is maintaining the stated HHCAHPS data requirements for CY 2013 set out in the CY 2012 final rule, for the continuous monthly data collection and quarterly data submission of HHCAHPS data. (Background on the HHCAHPS is at 77 FR 67094-5)

HHCAHPS oversight activities. In prior final rules, CMS indicated that vendors and HHAs would be required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines and survey requirements. All approved survey vendors must develop a Quality Assurance Plan for survey administration in accordance with the HHCAHPS Protocols and Guidelines Manual. Additional requirements include on-site visits by the HHCAHPS Survey Coordination Team of survey vendors. CMS proposed to codify the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. This requirement would be at §484.250(c).

In the final rule, CMS clarifies in response to comments that HHAs do not need to participate in vendor oversight activities and has modified the final rule language accordingly. However, CMS advises that 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 CMS becomes aware of a significant vendor issue that would put HHAs at risk for not meeting the APU requirements, it will immediately alert the affected HHAs. Also, "[i]f 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 CMS will remove that vendor from the approved list of HHCAHPS survey vendors."

HHCAHPS requirements for CY2014 and CY2015. In the proposed rule, CMS restated the reporting requirements that were included in the CY 2011 final rule:

> For the CY 2014 APU, CMS proposes to continue monthly HHCAHPS data collection and reporting for four quarters (the months of April 2012 through March 2013). HHAs receiving Medicare certification on or after April 1, 2012 are exempt for the CY 2014 APU. In addition, HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2011 through March 31, 2012 are exempt.
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> For the CY 2015 APU, CMS proposes to continue to require the continuous monthly HHCAHPS data collection and reporting for four quarters (the months of April 2013

through March 2014). HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2012 through March 31, 2013), that is, on or after April 1, 2013, are exempt for the CY 2015 APU. All HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2012 through March 31, 2013 are exempt.

HHCAHPS reconsideration and appeals process. The proposed rule included no changes to this process. CMS noted that HHAs have 30 days to send their reconsiderations to CMS and that CMS has and will continue to fully examine all HHA reconsiderations.

CMS is finalizing the proposed requirements for HHCAHPS as proposed. It is also codifying the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. CMS includes this at §484.250(c). The regulation is identically stated in the proposed rule and in this final rule.

4. Home Health Wage Index

In the proposed rule, CMS indicated that as in prior years, it would 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. CMS also would again use the labor market definitions as discussed in the Office of Management and Budget (OMB) Bulletin No. 03-04 (June 6, 2003) plus any subsequent bulletins regarding labor market changes. CMS continues to use the methodology discussed in the CY 2007 HH PPS final rule to address those geographic areas in which there were no IPPS hospitals and thus no hospital wage data on which to base the calculation of the HH PPS wage index.

CMS proposed that the labor-related share of the case mix adjusted 60-day episode rate for CY 2013 be 78.535% and the non-labor related share be 21.465%.

Comments included a variety of criticisms of the reclassified hospital wage index as the basis for the calculation of the home health wage index and not giving home health agencies a mechanism to seek geographic reclassification or to utilize the rural floor provisions that exist for inpatient PPS hospitals. CMS notes statutory constraints and recommendations of studies that have been conducted by MedPAC and CMS related to wage indices. Certain modifications may be addressed in future research activities.

In the final rule, CMS is implementing the home health wage index as proposed.

5. CY 2013 Payment Update

The final rule implements the payment rates as discussed below. In response to comments, and particularly about adverse effects of payment updates on HHAs that service beneficiaries in rural communities, CMS says that it will be looking to improve the accuracy of payment to HHAs in the future. As part of these efforts, it is conducting the mandated study under section 3131(d) of the ACA (due March 2014) on the development of HH payment revisions, an aspect of which is

to examine the costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas. 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.

National Standardized 60-Day Episode Rate

CMS is increasing the CY 2012 payment rate by 1.3% (and not the proposed 1.5%, reflecting updated data) and then reducing the rates by 1.32% to adjust for the observed nominal change in case mix, resulting in the final CY 2013 standardized 60-day episode payment rate of $2,137.73 for HHAs that submit the required quality measures. See the table below for details.

Final CY 2013 National 60-Day Episode Payment Amount Before Case-Mix Adjustment and Wage Adjustment		
Final CY 2012 National Standardized 60-Day Episode Payment rate for HHAs that Submit Required Data	CY 2013 National Standardized 60-Day Episode Payment rate for HHAs That Submit Required Data	CY 2013 National Standardized 60-Day Episode Payment rate for HHAs that Do Not Submit Required Data
$2,138.52	$2,137.73	$2095.52
From Tables 12 and 13, 77 FR 67100		

National Per Visit Rates Used to Pay the Low Utilization Payment Amount (LUPA) and to Compute Imputed Costs Used in Outlier Calculations

The final CY 2013 national per-visit rates are shown in below and vary for the six home health disciplines and by whether or not the HHA submits the required quality data.

Final CY 2013 National Per-Visit Payment Amounts		
Home Health Discipline Types	**For HHAs that Submit Required Quality Data**	**For HHAs that Do Not Submit Required Quality Data**
Home Health Aide	$51.79	$50.77
Medical Social Services	$183.31	$179.69
Occupational Therapy	$125.88	$123.39
Physical Therapy	$125.03	$122.57
Skilled Nursing Services	$114.35	$112.09
Speech Language Pathology Therapy	$135.86	$133.18
From Table 14. 77 FR 67101		

Under the final rule, CMS will update the LUPA payment amount by the CY 2013 home health payment update of 1.3 percent. The LUPA add-on payment to HHAs that do not submit quality data will be updated by the CY 2013 home health payment update (1.3 percent) minus two percentage points.

Final CY 2013 LUPA Add-On Amounts		
CY 2012 LUPA Add-On Payment Amount	**CY 2013 LUPA Add-On Payment Amount for HHAs That Submit Required Quality Data**	**CY 2013 LUPA Add-On Payment Amount for HHAs That Do Not Submit Required Quality Data**
$94.62	$95.85	$93.96
Table 15. 77 FR 67102		

Additional calculations are made to account for Nonroutine Medical Supplies (NRS) (see Tables 16-19 of the final rule at 77 FR 67102-3). CMS increases the CY 2012 NRS conversion factor ($53.28) by the final payment update of 1.3 percent, for a total of $53.97. Using that conversion factor for CY 2013, the payment amounts for the various severity levels are shown in Table 17. The different amounts for HHAs that do and do not submit the required quality data are shown in Tables 18 and 19.

Finally, under a change made by the ACA, payment amounts are increased for home health services furnished in rural areas by 3 percent for episodes and visits ending on or after April 1, 2010 and before January 1, 2016. The rural add-on is not subject to budget neutrality. 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 at 77 FR 67104-5.)

D. Home Health Face-to-Face Encounter

As discussed in both the preambles to the proposed and final regulations, existing rules require that, as a condition for home health payment, prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner (NPP) has had a face-to-face encounter with the patient. In the CY 2012 HH PPS final rule (76 FR 68597), CMS stated that, in addition to the certifying physician and allowed NPPs, the physician who cared for the patient in an acute or post-acute care facility, and who had privileges in such facility, could also perform the face-to-face encounter and inform the certifying physician, who would document the encounter as part of the certification of eligibility, and that the encounter supported the patient's homebound status and need for skilled services.

The home health industry asked CMS 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. The industry asserts that acute or post-acute care physicians utilize NPPs to obtain information about the patient's clinical condition and thus it would be reasonable and appropriate for an allowed NPP working in an acute or post-acute facility to perform the face-for-face encounter. Although the statute does not specifically address the situation of a NPP, it currently permits physician residents, under the supervision of a teaching physician, to perform the required face-to-face encounter. The teaching

physician, in turn, informs the certifying physician of the clinical findings of the face-to-face encounter, to include the patient's homebound status and the need for skilled services.

Since CMS recognizes this exchange of information between residents and teaching physicians as allowable under existing face-to-face requirements, the agency believes that NPPs should not be precluded from performing the face-to-face encounter in collaboration with the acute or post-acute care physician. Accordingly, CMS 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. CMS encouraged comment on these proposed changes. CMS said that in addition to meeting the goals of the face-to-face encounter provision, this proposed policy change would result in more efficient care coordination between the acute or post acute NPP and physician, and the certifying physician and that this more efficient care delivery will result in an improved transition of care from the acute or post-acute facility to the home health setting.

Regulatory text clarification. CMS also proposed to revise the regulatory language at §424.22(a)(1)(v)(D), so as to not be prescriptive as to what entity must "title" the face-to-face documentation but still require that it be signed by the certifying physician. CMS encouraged comment on this proposed change.

Comments and Final Rule

Many of the comments on this section of the proposed rule questioned the need for the face-to-face encounter requirement or the details of it, including how the new proposed flexibility in meeting this requirement would work, or sought clarification on how to comply with it under various circumstances.

CMS adopts the proposed policy as final without modification, including the change in the regulatory language described above.

E. Therapy Coverage Changes

Therapy Coverage and Reassessments. CMS currently requires that a qualified therapist (instead of an assistant) perform the needed therapy service, assess the patient, measure progress, and document progress toward goals at least once every 30 days during a therapy patient's course of treatment. For patients needing more than 13 or 19 therapy visits, a qualified therapist (instead of an assistant) must perform the therapy service required at the 13^{th} or 19^{th} visit, assess the patient, and measure and document effectiveness of the therapy.

The proposed rule described issues with these requirements. Currently, when a qualified therapist misses one of the required reassessment visits, once the therapist has completed the required reassessment, coverage resumes after this reassessment visit. Some agencies and therapists believe that the reassessment visit should be covered since therapy was also provided during that

visit even though it was not timely. Another issue relates to patients receiving more than one type of therapy and what happens if the required reassessment visit is missed for any one of the therapy disciplines for which therapy services are being provided. In this situation, the therapy visits are not covered for any of the therapy disciplines until the qualified therapist that missed the reassessment visit complies with the reassessment visit requirements. The home health industry believes this requirement is unfair in that it denies coverage for therapy disciplines that have met their requirement for qualified therapists to complete a reassessment visit and are providing what should be considered covered therapy services. CMS also noted in the proposed rule its concerns that this requirement may be adversely affecting beneficiaries' access to therapy services. If an HHA 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.

In response to these concerns, CMS proposed to revise §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. CMS expected this change to result in minimal changes to claims submissions but would monitor claims for unintended consequences, including possible up-coding associated with therapy-related home health resource groups (HHRGs) pre- and post-implementation.

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

CMS received generally favorable comments on these proposed changes and is adopting the changes as final without modification. The regulation text at §409.44(c)(2)(i)(E) has been revised to state that if a qualified therapist misses 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) is 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.

When Therapy Reassessment Visits are to be Conducted. Under current policy, if a patient lives in a rural area, or documented circumstances outside the therapist's control prevent her or him from completing the reassessment visit at the 13^{th} or 19^{th} visit, this requirement can be met by the therapist having made the visit during the 11^{th} or 12^{th} visit for the required 13^{th} visit or the 17^{th} or 18^{th} visit for the required 19^{th} visit. In the proposed rule, CMS noted that it continued to receive questions regarding acceptable visit ranges for the required 13^{th} and 19^{th} reassessment visits.

CMS said it also intends for similar flexibility to be applicable in cases where beneficiaries are receiving more than one type of therapy.

CMS thus 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 can 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.

Commenters generally favored the proposed changes although some raised additional concerns or sought clarifications. CMS is finalizing its proposal to revise the regulations at §409.44(c)(2)(i)(C)(1) and §409.44(c)(2)(i)(D)(1) with a modification 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. CMS also modifies the regulation 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.

F. Payment Reform: Home Health Study and Report

This section of the proposed rule described the progress on the ACA mandated study on home health care. In the final rule, CMS reports on comments (e.g., concerns about access problems for high-cost patients) and suggestions related to the study (e.g., using demonstrations to test revisions to the HHS PPS; modifying rebasing policy to achieve a fairer payment rate that does not discourage access to high-cost patients) and says that the latter will be taken into consideration when performing the study. CMS plans to provide updates regarding its progress in future rulemaking and open door forums. The agency is 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, HHS published a final rule relating to Administrative Simplification that sets a new compliance date for ICD-10-CM and ICD-10- PCS of October 1, 2014. CMS advises that it continues to work with the HH PPS Grouper maintenance contractor to revise the HH PPS Grouper to accommodate ICD-10-CM codes. The agency plans 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 website in conjunction with the release of the draft grouper in the summer/fall 2013. Providers will be updated on any changes to those plans through the: ICD-10 Home Health section of the CMS website; Home Health, Hospice and DME Open Door Forums; and provider outreach sessions for ICD-10.

CMS reiterates in the final rule's preamble that an analysis conducted by the HH PPS Grouper maintenance contractor for CMS revealed that many HHAs do not comply with the CMS guidelines relating to selection and assignment of OASIS Diagnoses, released in December 2008. The analysis demonstrated that HHAs are not limiting the number of diagnoses assigned to M1024 and continue to not comply with ICD-9-CM coding guidelines. CMS has reviewed the diagnosis codes identified in the HH PPS Grouper and confirmed that the only codes that cannot be reported as a primary or secondary diagnosis code (M1020 and M1022) are the fracture codes (V-codes). As a result, CMS proposed two enhancements for the HH PPS Grouper to encourage compliance with coding guidelines: (1) CMS would restrict M1024 to only permit fracture (V-code) diagnosis 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 enhance compliance with coding guidelines, CMS would pair the fracture codes (V-codes) with appropriate diagnosis codes and only when these pairings appear in the primary and payment diagnosis fields will the grouper award points. (2) CMS would revise 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. The rationale is that 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," and in doing so, CMS 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." CMS concludes that these actions will help ensure ICD-9 and ICD-10 coding guidelines are followed and will assist in the transition of grouping the diagnoses on the claim, versus OASIS, in determining the appropriate HIPPS code for payment.

Although some commenters supported CMS's plans for the ICD-10-CM transition as well as its plans to retire the payment diagnosis fields, others 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. Some wanted clarification and specificity regarding the reporting of the v-code. Some wanted CMS to update Attachment D to reflect changes in the OASIS and ICD-9-CM coding guidance. (In response to the latter, CMS agrees that the Attachment should be so updated.) Some were concerned that by preventing resolved conditions related to plan of care from being reported, CMS' proposed policy would result in the loss of significant information describing the patient. The final rule's preamble includes an extensive discussion of these and additional comments and CMS's responses, including its reporting on its analysis that shows a minimal impact of the proposed changes on overall HHA payments. (See 77 FR 67111-4.)

In response to comments, CMS is implementing the Grouper enhancements as proposed with two modifications. CMS will be modifying its 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 its pairing listing, the grouper will award points. CMS will also be modifying its policy for the payment diagnosis field to permit the reporting or 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.

III. Quality Reporting for Hospices

A. Background, Public Availability of Data

Under current law, hospices that fail to report required quality data will receive a 2 percentage point reduction in their market basket update.beginning with FY 2014. The Secretary is required to establish procedures for making quality data submitted by hospices available to the public. Procedures must also ensure that a hospice will have the opportunity to review the data regarding its program before the data are made public. In addition, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS Web site.

The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. CMS will announce the timeline for public reporting of data in future rulemaking.

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

In the final rule, CMS reiterates its proposed policy for hospice quality reporting and data submission for FY 2014 as summarized below. In response to comments (mostly supportive but some having concerns about individual measures), CMS is finalizing the proposed policy without modifications.

1. Quality Measures for Payment Year 2014

In the Hospice Wage Index under the FY 2012 Final Rule (76 FR 47302, 47320 (August 4, 2011)), to meet the quality reporting requirements for hospices for the FY 2014 payment determination, CMS 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 that pain was brought to a comfortable level within 48 hours. The data collection period is October 1, 2012 through December 31, 2012; the data submission deadline is April 1, 2013. The data are collected at the patient level, but 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. Specifically, hospices 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 is October 1, 2012 through December 31, 2012; 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. Stakeholder input will help inform future measure development.

CMS advises that hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they respond, not on how they respond or on performance level. No additional measures are required for payment year FY2014.

2. Data Submission Requirements for Payment Year 2014

CMS will provide a Hospice Data Submission Form to be completed using a web-based data entry site. Training will be provided to hospices through webinars and other downloadable materials before the data submission date. 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. (More information is at: www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/)

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

In the final rule, CMS reiterates its proposed policy for hospice quality reporting and data submission for FY 2015 as summarized below. In response to comments (mostly supportive but some having concerns about individual measures), CMS is finalizing the proposed policy without modifications.

1. Quality Measures for Payment Year 2015

To meet the quality reporting requirements for hospices for the FY 2015 payment determination and each subsequent year, CMS proposed that hospices report the two measures identified above for FY 2014: NQF #0209 and the structural measure: Participation in a QAPI Program that Includes at Least Three Quality Indicators Related to Patient Care. CMS will not extend the requirement that hospices provide a list of their patient care indicators.

2. Data Submission Requirements for Payment Year 2015

CMS advises that all hospice quality reporting periods subsequent to that for Payment Year FY 2014 will be based on a calendar year rather than a calendar quarter. 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.

D. Additional Measures under Consideration and Data Collection

CMS reiterates in the final rule's preamble the additional quality measures being considered and summarizes the comments received related to these measures. CMS's plans in terms of the specific quality measures and implementation timelines remain unchanged. Thus, for annual payment determinations beyond FY2015, CMS is considering an expansion of the required measures to include some additional measures endorsed by NQF. The measures of particular interest are NQF numbers 1634 (pain screening), 1637 (pain assessment), 1638 (dyspnea treatment), 1639 (dyspnea screening), and 0208 (family evaluation of hospice care) (see: www.qualityforum.org).

To support the standardized collection and calculation of quality measures specifically focused on hospice services, CMS believes the required data elements would potentially require a standardized assessment instrument. To achieve this, CMS has been working on the initial development and testing of a hospice patient-level data item set.[6] This could be used by all hospices in the future to collect and submit standardized data items about each patient admitted to hospice. These data could then be used for calculating quality measures. Many of the items currently in testing are already standardized and included in assessments used by a variety of other providers. Other items have been developed specifically for the hospice care settings, and obtain information needed to calculate the hospice-appropriate quality measures that were endorsed by NQF in February 2012. CMS is considering a target date for implementation of a standardized hospice data item set as early as CY 2014, dependent on development and infrastructure logistics.

In developing the standardized data item set, CMS has included data items that will support the following endorsed measures: 1617 (patients treated with an opioid who are given a bowel regimen); 1634; 1637; 1638 and 1639 (see above for definitions). Starting with data collection in 2015, CMS sees these as possible measures to implement, subject to future rulemaking.

CMS is 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. This could precede or follow the implementation of a standardized data set. CMS does 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.

[6] CMS has recently concluded a pilot test of a draft item set with nine hospices around the country providing services in various care settings, with the intent of getting a clear understanding of the implementation process and associated burdens on the hospices. (See 77 FR 67134.)

IV. Survey and Enforcement Requirements for Home Health Agencies

A. Background and Statutory Authority[7]

The HHA Conditions of Participation (CoP) apply to an HHA as an entity, as well as to the services furnished to each individual under the care of the HHA, unless the CoPs are specifically limited to Medicare/Medicaid beneficiaries, such as the OASIS requirements. 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 by statute to enter into an agreement with a State Survey Agency (SA) or a national accreditation organization, with oversight by CMS Regional Offices, to determine whether HHAs meet the federal participation requirements for Medicare. An SA is authorized by statute 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 HHAs. 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. Certain providers and suppliers, including HHAs, are also deemed by CMS to meet the federal requirements for participation if they are accredited by an accreditation organization whose program is approved by CMS to meet or exceed certain federal requirements. However, these deemed providers and suppliers are subject to validation surveys.

In the July 2012 NPRM, CMS proposed rules to implement survey and enforcement requirements, as well as establish alternative sanctions specified under §1891(f) of the Social Security Act (SSA) for HHAs.

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

1. General Provisions and Comments

CMS proposed to add new subparts I (re: survey and certification) and J (re: enforcement) to 42 CFR part 488 to implement provisions of OBRA ’87 to establish requirements for surveying and certifying HHAs and 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. CMS also would amend certain sections of 42 CFR part 488,

[7] The July 2012 proposed rule (and HPA summary of the rule) provides a more extensive discussion of the background and statutory authority for survey and enforcement requirements for HHAs.

subpart A – General Provisions (relating to survey, certification and enforcement for long term care facilities and their residents), to reference where appropriate HHAs and the patients they serve.

Several commenters urged CMS to 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. Some also submitted procedural questions regarding SA and CMS operations to implement the regulation. In response, CMS does not agree that an overall delay of the regulation is warranted. However, CMS will stage the effective date of the requirements "to permit more time for both dialogue and design of information system changes for effective administration of these provisions." Further, CMS will 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. CMS will share proposed guidance with stakeholders 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). Proposed §488.700 of subpart I would specify the statutory authority for and general scope of standards that establish the requirements for surveying HHAs to determine whether they meet the Medicare CoPs.

CMS is finalizing §488.700 of the 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.

(b) Definitions (§488.705). The proposed rule would define certain terms that have been part of longstanding CMS policy but have not yet been codified in the regulations for HHAs. In response to comments about specific definitions, CMS is making the following changes: (1) The broad scope of the definition of substandard care is retained (so as to refer to any CoP for which noncompliance was identified), but the definition is refined to focus on actual harm or potential for harm to the patient; (2) the definition of extended survey is revised 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). CMS proposed that a standard survey would be conducted not later than 36 months after the date of the previous standard survey. CMS would specify minimum requirements and provide that visits to homes of patients could be done only with the consent of the patient, their guardian or legal representative. The home visit would be to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of each patient as reflected in the patient's

written plan of care and clinical records. Other forms of communication with patients, such as through telephone calls, could be used to complete surveys, if determined necessary by the state SA or CMS Regional Office. The survey agency's failure to follow its own survey procedures would not invalidate otherwise legitimate determinations that deficiencies existed in an HHA.

CMS received only two comments, both advocating for more frequent surveys than proposed. In response, CMS says that this policy, while facilitating a more focused approach, will enable them to conduct more frequent surveys in the case of HHAs with higher risks of quality of care problems. CMS adopts the proposed rule as final without modification.

(d) Partial Extended Survey (§488.715). A partial extended survey would be conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. It would be conducted when a standard-level noncompliance was identified or if the surveyor believed that a deficient practice existed at a standard or condition-level that was not examined during the standard survey. The surveyor would review, at a minimum, additional standard(s) under the same CoP in which the deficient practice was identified during the standard survey. Surveyors could also review any additional standards under the same or related CoPs which would assist in making a compliance decision. Consistent with certain CMS standards for other providers, the SA would certify that a provider is not in compliance with the CoPs where the deficiencies are of such character as to substantially limit the provider's capacity to furnish adequate care or which adversely affect the health and safety of patients. A CoP may be considered out of compliance (and thus condition-level) for one or more standard level deficiencies, if, in a surveyor's judgment, the standard-level deficiency constitutes a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes.

CMS adopts the proposed language as final without modification.

(e) Extended Surveys (§488.720). These surveys would review compliance with all CoPs and standards applicable to the HHA. They could be conducted at any time, at the discretion of CMS or the SA, but would be conducted when any condition-level deficiency was found. They also would review the HHA's policies, procedures, and practices that produced the substandard care (i.e., noncompliance with one or more CoP at the condition-level). An extended survey would be conducted no later than 14 calendar days after the completion of a standard survey which found the HHA had furnished substandard care and would review any associated activities that might have contributed to the deficient practice.

In response to comments asking that the definition of substandard care and the association of that definition with an extended survey be clarified, CMS has adopted the proposed rule with changes. In addition to revising the definition of substandard care (see §488.705 above), CMS is clarifying the provision at §488.720 to state that the extended survey reviews "additional" conditions that were not evaluated during the standard survey. CMS has also revised §488.720(b) to require the extended survey to 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). Under the proposed rule, surveys would have to be conducted with procedures and scheduling that renders the onsite surveys as unpredictable in their timing as possible. CMS would 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. Any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey would be subject to a civil money penalty (CMP) not to exceed $2,000.

CMS received no comments on these proposals and is finalizing them without modification.

(g) Survey Frequency and Content (§488.730). Under the proposed rule, each HHA would have to be surveyed not later than 36 months after the last day of the previous standard survey. In addition, a survey may be conducted as frequently as necessary to assure the delivery of quality home health services by determining whether an HHA complies with the law and CoP and to confirm that the HHA has corrected previously cited deficiencies. A standard survey or an abbreviated standard survey may be conducted within 2 months of a change in ownership, administration or management of the HHA. A standard or abbreviated standard survey would have to 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 as otherwise required to determine compliance with the CoP such as the investigation of a complaint. 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.

Commenters urged more frequent surveys specific to complaints and substandard care issues. Some urged some complaints be investigated within 48 hours. In response, CMS says that while it agrees that frequent HHA surveys are desirable, its approach is to conduct more frequent surveys of those HHAs that available information indicates have a higher risk of quality of care issues. CMS maintains a complaint tracking and prioritization system which prioritizes complaints according to the level of risk for the patients at the HHA; those that indicate the possibility of an immediate jeopardy situation are given the highest priority and are investigated as soon as possible. CMS will take into consideration suggestions about timeframes for investigations as it develops interpretive guidance. The final rule adopts the proposed language without changes.

(h) Surveyor Qualifications (§488.735). Under the proposed rule, surveys would have to be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any state or federal surveyor could serve on an HHA survey team (except as a trainee), he/she would have to successfully complete the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites. All surveyors would have to follow specified principles for determining compliance with the CoP. A surveyor would be prohibited from surveying an HHA if he/she has served on the staff or as a consultant to the HHA undergoing the survey. This prohibition would also apply if the surveyor has a financial interest

or an ownership interest in the HHA to be surveyed; has a family member who has a relationship with the HHA to be surveyed; or has an immediate family member who is a patient of the HHA to be surveyed.

Commenters urged that the criteria for qualified surveyors be strengthened, that there be more consistency in training, or that a surveyor be disqualified if he/she worked at a competitor of the HHA being surveyed within the last two years. Other comments included that CMS should allocate funds annually for national training of the HHA industry in the CoPs and alternative sanction policies.

The final rule adopts the language as proposed. CMS says that some of these issues may be addressed in implementing guidance.

(i) Certification of Compliance or Noncompliance (§488.740). The proposed rule would cross-reference the rules for certification, documentation of findings, period review of compliance and approval, certification of non-compliance and determining compliance for HHAs that are set forth in other sections of this part of the CFR (§488.12, §488.18, §488.124 and §488.26) to be followed when a State Agency certifies compliance or non-compliance of the HHA with the law and CoPs. This language has been adopted in the final rule without change.

(j) Informal Dispute Resolution (IDR) (§488.745). The proposed rule provided that upon the provider's receipt of an official statement of deficiencies, an HHA would be afforded the option to request an informal opportunity to dispute condition-level survey findings. Failure of CMS or the State, as appropriate, to complete an IDR would not delay the effective date of any enforcement action. If any findings were revised or removed by CMS or the State based on an IDR, the official statement of deficiencies would be revised accordingly and any enforcement actions imposed solely as a result of those cited deficiencies adjusted accordingly.

When the survey findings indicate a condition-level deficiency, CMS or the state, as appropriate, would have to provide the HHA 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 would have to be submitted in writing to the state or CMS, include the specific deficiencies in dispute, and should be made within the same 10 calendar day period that the HHA has for submitting an acceptable plan of correction.

Some commenters supported CMS' introduction of an IDR but urged that CMS delay the imposition of a sanction until the completion of the IDR process, a recommendation that CMS rejects saying that its policy balances the needs of HHAs to avoid unnecessary disputes and protracted litigation, on one hand, with the interests of HHA patients, (which CMS sees as paramount) in assuring the most rapid correction of deficiencies. Some urged that the IDR be available for standard-level as well as condition-level deficiencies. In response, CMS explains that the IDR's purpose is for the HHA to dispute condition-level findings that may be an impetus for an alternative sanction and standard-level findings alone do not trigger an alternative sanction. Other questions related to timeframes and other matters may be addressed in guidance,

internal policy directives and SA performance standards. CMS is finalizing the section as proposed.

3. Subpart J--Alternative Sanctions for Home Health Agencies with Deficiencies

(a) Statutory Basis. CMS reiterates in the final rule the statutory basis for this section. Under the statute, CMS may terminate an HHA's provider agreement if that HHA is not in substantial compliance with Medicare requirements. It may also terminate one 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. OBRA '87 expanded the Secretary's enforcement options. If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that an HHA certified for Medicare participation is no longer in compliance 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 must take immediate action to remove the jeopardy and correct the deficiencies or terminate the certification of the HHA, and may provide, in addition, for one or more of other specified sanctions.

CMS set out the statutory basis for the new subsection at proposed §488.800, providing for termination of HHAs that fail to comply with CoPs. CMS also proposed procedures with respect to the conditions under which each of the alternative sanctions developed by the Secretary are designed, with the goal of minimizing the time between identification of deficiencies and imposition of sanctions, including incrementally more severe fines for repeated or uncorrected deficiencies. The section also stated that these sanctions are in addition to any others available under State or federal law, and, except for CMPs, are imposed prior to the conduct of a hearing.

In the final rule's preamble, CMS responds to some criticisms of their proposals by referencing and explaining the statutory authority. CMS adopts the provisions in this section as final without change.

(b) Definitions (§488.805). CMS proposed in the July 2012 NPRM to add §488.805 to define frequently used terms. Although §1891 of the SSA uses the term "intermediate sanctions," for consistency with other enforcement rules, the proposed rule used "alternative sanctions" to have the same meaning. In response to comments, the final rule includes revised definitions for "repeat deficiency" and "temporary management," and adopts the remaining definitions as proposed. "Repeat deficiency" is defined as "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." CMS will publish further guidance in the State Operations Manual to surveyors for identifying and citing repeat deficiencies. The definition of "temporary management" has been revised 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). In the July 2012 NPRM, CMS proposed that when CMS chooses to apply one or more sanctions specified in §488.820, they be applied on the basis of noncompliance with CoPs found through surveys and may be based on failure to correct previous deficiency findings as evidenced by repeat deficiencies. One or more sanctions could be imposed for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance. A sanction would apply to the parent HHA and its respective branch offices but not to an associated subunit. Regardless of which sanction was applied, a noncompliant HHA would have to submit a plan of correction for approval by CMS. CMS would provide written notification to the HHA of the intent to impose the sanction.

In addition, CMS proposed that an HHA could request a hearing on a determination of noncompliance leading to the imposition of a sanction, including termination of the provider agreement. A pending hearing would not delay the effective date of a sanction, including termination. Sanctions would continue to be in effect regardless of the timing of any appeals proceedings.

In the final rule, these provisions are adopted without change except for the removal of a sentence that was found by commenters to be confusing. As a result, the final rule says that "when CMS imposes a sanction, the sanction applies to the parent HHA and its respective branch offices." The final language deletes the following "The sanctions imposed on a parent and/or its respective branches do not apply to the associated subunit."

(d) Factors to be Considered in Selecting Sanctions (§488.815). In the July 2012 NPRM, CMS proposed to base its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to:

- The extent to which the deficiencies pose immediate jeopardy to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies, the HHA's overall compliance history and any history of repeat deficiencies at either the parent or branch location.
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the HHA is part of a larger organization with performance problems.
- An indication of any system-wide failure to provide quality care.

CMS proposed to apply its statutory authority to provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. (These terms were defined.)

These provisions have been adopted under the final rule, without modification. CMS responds to commenters seeking more detailed instruction on the selection of sanctions that it will provide

these in interpretative guidance and also provide extensive training for SAs and Regional Offices on the factors for the selection of sanctions.

(e) Available Sanctions (§488.820). Under the proposed rule, the following alternative sanctions would be available in addition to termination of the provider agreement: CMPs; suspension of payment for all new admissions and new payment episodes; temporary management of the HHA; directed plan of correction; and directed in-service training.

CMS is finalizing this section as proposed. In response to a comment, CMS notes that it plans to expand its tracking system for alternative sanctions in long term care to include them for HHAs.

(f) Action when Deficiencies Pose Immediate Jeopardy (§488.825) and Termination (§489.53). CMS proposed that if there is immediate jeopardy to the HHA's patients' health or safety, that it immediately terminate 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. In addition, CMS may impose one or more alternative sanctions, as appropriate. CMS would give the HHA at least two days notice in advance of the enforcement action. An HHA, if its provider agreement terminated, would be 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.

Based on the comments received, HHS is finalizing this section as proposed.

(g) Action when Deficiencies Are at the Condition-level but Do Not Pose Immediate Jeopardy (§488.830). In the July 2012 NPRM, CMS noted its interest in providing incentives for HHAs to achieve and maintain full compliance with program requirements before termination becomes necessary, and reflected this in the following:

- If the HHA is no longer in compliance with the CoPs, either because the deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, or because the HHA has repeat noncompliance with standard-level deficiencies or repeat condition-level deficiencies that would lead to noncompliance based on the HHA's failure to correct and sustain compliance as described in their proposed plan of correction, CMS would: (1) terminate the HHA's provider agreement; or (2) in addition to, or as an alternative to termination for a period not to exceed six months, impose one or more alternative sanctions. Except for CMPs, for all sanctions when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action.

- If an HHA does not meet the criteria for continuation of payment, CMS will terminate the HHA's provider agreement within 6 months of the last day of the survey, if the HHA is not in compliance with the CoPs and the terms of the plan of correction have not been met.

- If a HHA's provider agreement is terminated, it would be 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 would have to assist HHA in the safe and orderly transfer of care and services for the patients to another local HHA.

Based on the comments, CMS is finalizing these proposed provisions with minor technical modifications for grammar.

(h) Temporary Management (§488.835). CMS proposed when and how it would apply temporary management, the duration of this sanction, and the payment procedures for temporary managers. Temporary management is temporary appointment by CMS or a CMS authorized agent of an authorized substitute manager or administrator (based on specified qualifications) who would be under the direction of the HHA's governing body and who would have authority to hire, terminate or reassign staff, obligate HHA funds, alter HHA procedures, and manage the HHA to correct deficiencies identified in the HHA's operation. CMS could impose temporary management when it has determined 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. CMS would impose temporary management to bring an HHA into compliance with program requirements in non-immediate jeopardy cases within six months. CMS could choose to impose temporary management as a sanction for deficiencies that posed immediate jeopardy to patient health and safety. When temporary management is imposed, CMS would consider the HHA's or SA's recommendation for a temporary manager when making the appointment. Each state SA would be required to maintain a list of recommended individuals eligible to serve as temporary managers, and annually submit the list to CMS.

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

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

Temporary management would be provided at the HHA's expense. Before the temporary manager was installed, the HHA would have to agree to pay his/her salary as well as other benefit costs directly for the duration of the appointment. The salary for the temporary manager would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type, based on the Geographic Guide by the Department of

Labor (BLS Wage Data by Area and Occupation).

CMS adopts the proposed rule with a technical modification. It has removed language prohibiting the costs of the temporary manager as an allowable cost on the cost report. In response to comments that CMS use temporary management only in extraordinary circumstances, that any temporary manager be bonded and that the HHA be given the choice of three possible temporary managers, CMS responds that it will develop guidance for this provision that will provide specific direction to the SAs and Regional Offices. This 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. CMS does not believe it necessary to require that the temporary manager be bonded.

(i) Suspension of Payment for All New Admissions and New Payment Episodes (§488.840). Under the proposed rule, if an HHA had a condition-level deficiency or deficiencies (regardless of whether or not immediate jeopardy existed), CMS would suspend payments for new Medicare patient admissions to the HHA that were made on or after the effective date of the sanction. "New admission" was specifically defined. The suspension period would not exceed six months and would end when the HHA either achieved substantial compliance or was terminated. Suspension of payment for new patient admissions and for new payment episodes that occurred on or after the effective date of the sanction could be imposed any time an HHA was found to be out of substantial compliance. CMS would provide the HHA with written notice of non-compliance at least two calendar days before the effective date of the sanction in immediate jeopardy situations or at least 15 calendar days in non-immediate jeopardy situations. The notice would include the nature of the non-compliance; effective date of the sanction; and the right to appeal the determination leading to the sanction. The suspension of payment sanction would end when the HHA was determined to have corrected all condition-level deficiencies, or upon termination, whichever was earlier. Once a sanction was imposed, the HHA would be required to notify any new patient admission and patients with new payment episodes—before care could be initiated—that Medicare payment might not be available to this HHA because of the imposed suspension. The HHA would be precluded from charging the Medicare patient for those services unless it could show that, before initiating or continuing care, it had notified the patient or his/her representative both orally and in writing in a language that the patient or representative could understand, that Medicare payment might not be available. The suspension of payment would end when CMS terminated the provider agreement or CMS found the HHA to be in compliance with all CoPs.

Further, under the proposed rule, if CMS terminated the provider agreement, or if the HHA was in substantial compliance with the CoPs (as determined by CMS), the HHA would not be eligible for any payments for services provided to new Medicare patients admitted during the time the suspension was in effect, or for existing Medicare patients beginning a new payment episode during their care. This policy would be consistent with the legislative history of OBRA '87. If compliance with the CoPs was achieved, CMS would resume payment to the HHA prospectively from the date that CMS had determined correction. The suspension of payment would end when CMS terminates the provider agreement or CMS finds the HHA to be in substantial compliance with all of the CoPs.

Based on comments, CMS has adopted the proposed language with modifications. Commenters said that the use of payment suspension for new payment episodes would be detrimental to a HHA in its efforts to make corrections needed to confirm compliance and would be disruptive to patients. CMS agrees that suspension of new payment episodes may be disruptive to patients as they would have to transfer to different HHAs with different staff as well as difficult for the HHA to maintain a caseload of patients to ensure compliance. In the final rule, CMS has retained the suspension of payment for new payments as an option but has removed references to new payment episodes from the suspension of payment sanction as well as the definition of "new admission."

(j) Civil Money Penalties (§488.845). The law authorizes CMS to 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. CMS may impose a CMP for the number of days of immediate jeopardy, the amount of which cannot exceed $10,000 for each day of non-compliance. A deficiency found during a survey at a parent HHA or any of its branches results in a noncompliance issue for the entire HHA, which can be subject to the imposition of a CMP.

CMS proposed both "per day" and "per instance" CMPs. A "per instance" CMP may range from $1,000 to $10,000. Under the proposed rule, the following factors would be considered when determining a CMP amount in addition to the factors considered when choosing a type of sanction:

- 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 the Provider Enrollment, Chain, and Ownership System (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 CoPs and to ensure patient health and safety.

CMS further proposed that 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. Within the statutory limits of $10,000 per day of noncompliance, CMS would have the discretion to increase or reduce the amount of CMP during the period of noncompliance depending on whether the level of noncompliance had changed at the time of a revisit survey. Three ranges of CMP amounts were proposed based on the level of seriousness:

- Upper range – For a deficiency that poses immediate jeopardy to patient health and safety, CMS would assess the penalty within the range of $8,500 to $10,000 per day of condition-level noncompliance.
- Middle range – For repeat and/or a condition-level deficiency that did not pose immediate jeopardy, but is directly related to poor quality patient care outcomes, CMS would assess a penalty within the range of $2,500 to $8,500 per day of noncompliance with the CoPs.
- Lower range – For repeated and/or condition-level deficiencies that did not constitute immediate jeopardy and were deficiencies in structures or processes that did not directly relate to poor quality patient care, CMS would assess a penalty within the range of $500 to $4,000 per day of noncompliance.

CMS proposed to send an HHA written notice of the intent to impose a CMP, including the amount and the proposed effective date of the sanction. After a final agency determination is made, a final notice would be sent with the final amount due and the rate of interest to be charged on unpaid balances (as published quarterly in the *Federal Register)*. The notice content is specified (see the final rule at 77 FR 67152). The HHA would have 60 days from the receipt of the notice to request an administrative hearing or waive its right to such hearing in writing and receive a 35 percent reduction in the CMP amount. This reduction would be offered to encourage HHAs to address deficiencies more expeditiously and to save the cost of hearings and appeals. Upon such reduction, the CMP would be due within 15 days of the receipt of the HHA's written request for waiver. The HHA could waive its right to a hearing in writing within 60 calendar days from the date of the notice initial determination. The per-day CMP would begin to accrue on the day of the survey that identified the HHA noncompliance, and would end on the date of correction of all deficiencies, or the date of termination. In immediate jeopardy cases, if the immediate jeopardy was not removed, the CMP would continue to accrue until CMS terminated the provider agreement (within 23 calendar days after the last day of the survey which first identified the immediate jeopardy). If immediate jeopardy did not exist, the CMP would continue to accrue until the HHA achieved substantial compliance or until CMS terminated the provider agreement, whichever was earlier.

CMS also proposed that the per-day and per-instance CMP not be imposed simultaneously in conjunction with a survey. In no instance would 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 did not achieve compliance with the CoPs within those 6 months, CMS would terminate the HHA. The accrual of the CMP would stop on the day the HHA provider agreement was terminated or the HHA achieved substantial compliance, whichever was earlier. Total CMP amounts would be computed after final CMS determination: (1) compliance was verified; (2) the HHA provider agreement was involuntarily terminated; or (3) administrative remedies had been exhausted. Additional related procedures, including timing of payments, notices, and opportunity for a hearing were also proposed.

Comments on the proposed policies in this section took issue with the size and application of the proposed penalties as well as the criteria that would trigger a penalty. In response, CMS has made some changes in the final rule although most of it has been adopted as final. The most

significant changes relate to the size of the middle range penalties. Under the revised language, the three tiers of penalties are as follows:

- Upper range—For a deficiency that poses immediate jeopardy to patient health and safety, a penalty could be assessed within the range of $8,500 to $10,000 per day of condition-level noncompliance. Specifically, CMS 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), CMS will impose a CMP of $9,000 per day. For an isolated employee incident of noncompliance in violation of established HHA policy, CMS 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, the penalty would be 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, the penalty would be within the range of $500 to $4,000 per day of noncompliance.

Offsets. Under the proposed rule, the amount of any penalty would be deducted (offset) from any sum that 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 at a rate based on the Medicare interest rate published quarterly in the *Federal Register*. CMP receipts not recovered due to HHA failure to pay or inadequate funds for offset would 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, CMS would collect the CMP through offset of monies owed or owing to the HHA. A proposed process for doing this was described.

CMS received no comments on this section and the proposed rule is adopted as final without modification.

Disbursement of recovered CMP funds. CMS had 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 SSA, using average expenditures from 2007 to 2009. Approximately 63% of the CMP amounts recovered would be deposited as miscellaneous receipts to the U.S. Department of the Treasury and approximately 37% would be returned to the state Medicaid Agency to improve the quality of care for those who need home-based care. Beginning one year after these rules were finalized and became effective, these proportions would be updated annually based on the most recent 3-year period for which CMS determined that the Medicare and Medicaid expenditure data were essentially complete.

CMS adopts its proposed policy as final.

Costs of home health surveys. In the preamble to the proposed rule, CMS said that consistent with the proposed disbursement to States of a portion of federally imposed CMP amounts collected, CMS would require state Medicaid programs to share in the cost of HHA surveys for those HHAs that are Medicaid-certified. Section §431.610(g) (relations with standard-setting and survey agencies) would be amended to apply to HHA surveys the same cost accounting principles that are now applied to nursing homes. CMS projected the initial cost to the Medicaid program to be approximately 37 percent of the cost of surveys for dually-certified programs. CMS asked for comment on this new proposed requirement for State Medicaid programs and the methodology for calculating the state share of both survey costs and CMP disbursement.

In response to comments saying that states should not share in the costs of performing surveys, CMS has decided to removed the propose rule provision at §431.601(g) in this final rule.

(k) Directed Plan of Correction (§488.850). CMS proposed a directed plan of correction as an available sanction. Specifically, CMS would be able to impose such a correction on an HHA which is out of compliance with the CoPs. It would require the HHA to take specific actions in order to correct the deficient practice(s) if the HHA failed to submit an acceptable plan of correction. The directed plan of correction would have to be developed by CMS or by the temporary manager, with CMS' approval. It would set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes, and the specific date the HHA would be expected to achieve such outcomes. If the HHA failed to achieve compliance within the timeframes specified in the directed plan of correction, CMS would impose one or more additional alternative sanctions until the HHA achieved compliance or was terminated from the Medicare program. Before imposing this sanction, CMS would provide appropriate notice to the HHA of this sanction.

The proposed language is adopted as final without modification.

(l) Directed In-service Training (§488.855). CMS proposed that directed in-service training would be used in situations where staff performance resulted in deficient practices. Such program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes. It would be imposed if CMS determined that the HHA had a deficiency or deficiencies that indicated noncompliance, and that staff education was likely to correct the deficient practice(s). It could be imposed alone or in addition to other alternative sanctions. HHAs would be required to use in-service programs conducted by instructors with an in-depth knowledge of the area(s) that would require specific training, so that positive changes would be achieved and maintained. HHAs would be required to participate in programs developed by well-established centers of health services education and training. CMS would only recommend possible training locations to an HHA and not require that the HHA utilize a specific school/center/provider. If the HHA did not achieve compliance after such training, CMS could impose one or more additional sanctions. The HHA itself would pay for the directed in-service training for its staff.

The proposed language is adopted as final without modification.

(m) Continuation of Payments to HHAs with Deficiencies. The law authorizes the Secretary to continue Medicare payments to HHAs not in compliance with the CoPs for up to six months if: the SA finds it more appropriate to impose alternative sanctions to assure compliance with program requirements than to terminate the HHA from the Medicare program; the HHA submits a plan of correction to the Secretary; and the HHA agrees to repay the federal government the payments under this arrangement should the HHA fail to take the required corrective action by the time of the revisit. CMS proposed to codify these three criteria in the regulations.

If any of these requirements were not met, an HHA with condition-level deficiencies would not receive any federal payments from the time that deficiencies were initially identified. CMS would terminate the agreement before the end of the 6-month correction period if the requirements were not met. If any sanctions were also imposed, they would stop accruing or end when the HHA achieves compliance with all requirements, or when the HHA's provider agreement was terminated, whichever was earlier. CMS would terminate the HHA's provider agreement if the HHA was not in compliance with the CoPs within 6 months of the last day of the survey. Finally, if an HHA provided an acceptable plan of correction but could not achieve compliance with the CoPs within 6 months of the last day of the survey, CMS would terminate the provider agreement.

The proposed language is adopted as final without modification.

(n) Termination of Provider Agreement (§488.865). Under the proposed rule, termination of the provider agreement would end all payments to the HHA and end any alternative sanctions imposed against the HHA, regardless of any proposed timeframes for the sanction(s) originally specified. The provider agreement would be terminated if the HHA failed to: (1) correct condition-level deficiencies within six months unless the deficiencies constituted immediate jeopardy; (2) submit an acceptable plan of correction for approval by CMS; (3) relinquish control to the temporary manager, if that sanction had been imposed or (4) meet the eligibility criteria for continuation of payments under proposed §488.860. If CMS or the SA determined deficiencies existed which posed immediate jeopardy to patient health and safety, CMS would terminate the provider agreement. The provider could also voluntarily terminate its agreement. CMS and the SA would, if necessary, work with all Medicare-approved HHAs that were terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA. Procedures for terminating a provider agreement are specified, including the opportunity for appeal and notice requirements.

In the preamble to the final rule, CMS addresses some commenters' concerns that CMS would not be affording due process with the implementation of sanctions, including CMPs, before the HHA has been allowed full access to appeal and the appeal is resolved. CMS does not believe that these concerns have merit and explains that this policy honors the intent of the Act to impose remedies as soon as possible in order to protect patients. CMS adds that "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."

The proposed rule is adopted as final without changes.

C. Provider Agreements and Supplier Approval

CMS proposed to amend §498.3 relating to scope and applicability to include specific reference to HHAs and to cross-refer to the proposed §488.740 concerning appeals. CMS has finalized these provisions as proposed.

D. Solicitation of Comments

CMS currently is required only to give notice of an HHA termination to the public 15 days before the effective date of an involuntary termination. In the proposed rule, CMS asked for comments on additional public notices. CMS advised that it was considering that when a suspension of payments for new admissions and new payment episodes or a CMP is imposed, it could, at its discretion, issue a public notice, thereby making such information available to patients who were choosing a provider of home health services, as well as to current recipients of home health care. Right now, a 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. CMS also sought comments on the proposed definition of "per instance" of noncompliance when imposing a CMP sanction.

CMS notes in the final rule's preamble that it received many comments opposed to any public notice other than for termination. In response, CMS notes that it agrees with the concerns raised by commenters and is not including in the final rule a requirement for public notice when alternative sanctions are imposed.

V. Collection of Information Requirements

CMS finds that the information reporting requirements associated with the final rules related to HHAs and hospice quality reporting do not add new burdens that would require CMS to document new costs under the Paperwork Reduction Act. (For further details on this section, see the final rule at 77 FR 67156-7.)

VI. Regulatory Impact Analysis

CMS advises that this final rule does not reach the required economic threshold needed to be considered a major rule.

Net Impact

CMS estimates that the net impact of the proposals 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 fixed dollar loss (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 overall .01 percent reduction for all HHAs, however, varies by type and location of HHAs as highlighted in Table 28 (77 FR 67159-67160).

The Regulatory Flexibility Act (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. The Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities where small HHAs are defined as either non-proprietary or proprietary with total revenues of $13.5 million or less in any 1 year. Analysis of Medicare claims data reveals a 0.05 percent decrease in estimated payments to small HHAs in CY 2013.

CMS cautions that its impact analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based on Medicare claims from 2010. Certain events may combine to limit the scope or accuracy of the analysis, because it 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.

Survey and Enforcement Requirements for Home Health Agencies

The RFA requires agencies to analyze options for regulatory relief of small entities. CMS is not preparing an analysis for the RFA because it has 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. CMS says that the benefit will be in assuring public health and safety but that the final rule will have a minor impact on HHAs and SAs. (Data to support this are included in this section of the preamble.)

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. CMS estimates that these provisions will cost the agency annually about $410,972.

VII. Federalism Analysis

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