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

July 17, 2012

On July 6, 2012, the Centers for Medicare & Medicaid Services (CMS) made public a proposed rule for the CY 2013 update to the Medicare home health prospective payment system (HH PPS) (CMS-1358-P). The proposed rule was published in the July 13, 2012 *Federal Register* (77 FR 41548 to 41600). Included is an update to the market basket, case-mix adjustments due to variation in costs among different units of services, adjustments for geographic differences in wage levels, outlier payments, submission of quality data and additional payments for services provided in rural areas. The preamble includes a discussion of the proposed case-mix up-coding adjustment and a proposal to increase flexibility regarding therapy documentation and assessments and face-to-face encounter requirements. In addition, CMS proposes new requirements concerning the hospice quality reporting program. The proposed rule also would establish requirements for unannounced, standard, and extended surveys of home health agencies (HHAs) and provide a number of alternative (i.e., intermediate) sanctions if HHAs were out of compliance with Federal requirements. **Comments on the proposed rule are due by September 4, 2012.**

The proposed 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 $2,141.95 (for those home health agencies (HHAs) that submit the required quality measures). The comparable final rate is $2,206.21 when home health services are provided in a rural area.[1] The comparable CY 2012 urban payment rate is $2,138.52 while the rural rate is $2,159.23.

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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.

I. Impact[2]

CMS estimates the overall impact of the proposed rule would result in a decrease of about 0.1 percent for a total of $20 million in Medicare savings for CY 2013. The proposed decrease reflects the distributional effects of an updated wage index ($70 million decrease), a +1.5 percent home health payment update ($300 million increase) and the -1.32 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($250 million decrease). The overall 0.1 percent reduction for all HHAs, however, varies by type and location of HHAs as highlighted in Table 25 (77 FR 41589-90). As CMS observes, in general, facility-based, proprietary agencies in rural areas would be positively affected as a result of the proposed provisions of this rule. In addition, free-standing, other volunteer/non-profit agencies and facility-based volunteer/non-profit agencies in urban areas would be affected positively. The following shows extracts from the referenced table.

Proposed Home Health Agency Policy Impact for CY 2014, by Facility Type and Area of the Country	
Group	**Proposed Impact of all CY 2013 Policies**
All home health agencies	-0.10%
Non-profit HHAs	
Free-Standing	+0.32%
Facility-Based	+0.20%
Proprietary HHAs	
Free-Standing	-0.23%
Facility-Based	-0.11%
Government-owned HHAs	
Free-Standing	-0.19%

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

Proposed Home Health Agency Policy Impact for CY 2014, by Facility Type and Area of the Country	
Group	**Proposed Impact of all CY 2013 Policies**
Facility-Based	-0.22%
Urban HHAs	-0.02%
Rural HHAs	-0.48%
Table 25, Proposed Home Health Agency Policy Impacts for CY 2013, By facility Type and Area of the Country, 77 FR 41589-90.	

II. Provisions of the Proposed Rule

A. Case Mix Measurement

Every year since the HH PPS CY 2008 proposed rule, CMS has advised that it continues to monitor case-mix changes in the HH PPS and to update its analysis to measure changes in case-mix, both real and changes which are unrelated to changes in patient acuity (nominal). The latest analysis by CMS continues to support the need to make payment adjustments in CY 2013 to account for nominal case-mix change.

Although CMS received critical feedback on its methodology, the agency included for the CY 2011 HH PPS final rule a 3.79 percent reduction to account for the observed case-mix growth attributable to documentation and coding. CMS held off adopting a similar reduction for CY 2012, however, pending more complete data. CMS also commissioned a study by a team from Harvard University to conduct an independent review of its methodology. The independent review concluded that the CMS model would be improved by incorporating variables from the Hierarchical Condition Categories (HCC) data.[3] After running the model as augmented by the HCC data, CMS obtained a final nominal case-mix change measure of 19.03 percent from 2000 to 2009.

For this CY 2013 proposed rule, CMS has 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 estimates that 15.97 percent of the total percentage change in the national average case-mix weight since the interim payment system baseline through 2010 is due to changes in real case-mix. When taking into account the total measure of case-mix change and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, CMS obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010. CMS notes that its estimates of real and nominal case-mix change are consistent with past results. "Most of the case-mix change has been due to improved coding, coding practice changes, and other behavioral responses to the prospective payment system, such as increased use of high therapy treatment plans." (See Table 1 (77 FR 41553) for a summary of real and nominal case-mix change estimates: 2000-2010.)

[3] The HCC data are used by CMS to risk-adjust payments to Medicare Advantage plans.

CMS says that to fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which has been accounted for in previous payment reductions, the percentage reduction to the national standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. **CMS is thus considering proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, and is seeking comments on that proposal,** rather than moving forward with the 1.32 percent reduction promulgated in last year's CY 2012 HH PPS final rule. That said, CMS proposes for CY 2013 to move forward with the 1.32 percent payment reduction to the national standardized 60-day episode rates as promulgated in the CY 2012 HH PPS Final Rule (76 FR 68532).

B. Outlier Policy

Background and Statutory Update

CMS notes that prior to the enactment of the Affordable Care Act (ACA), program requirements provided that outlier payments not exceed 5 percent 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 percent 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 has been to reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do this for CY 2012, CMS first returned the 2.5 percent held for the target CY 2010 outlier pool to the national standardized 60-day episode rates, the national per visit rates, the 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 percent. For CY 2011 and subsequent calendar years, CMS targets up to 2.5 percent of estimated total payments to be paid as outlier payments, and applies a 10 percent agency-level outlier cap.

Loss-Sharing Ratio and Fixed Dollar Loss (FDL) Ratio. CMS explains 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 percent 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 percent of the additional estimated costs above the outlier threshold amount.

CMS is not proposing a change to the loss-sharing ratio in this proposed rule. In the CY 2011 HH PPS final rule (75 FR 70398), in targeting total outlier payments as 2.5 percent of total HH PPS payments, 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 percent of the additional estimated costs.

CMS describes its methodology for updating the FDL but is proposing no change to it. This is, "in part because we have not been able to verify these projections in our paid claims files since we implemented the 10 percent agency-level cap on outlier payments on January 1, 2010." Another consideration is "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 advises that for the final rule, the agency will update its estimate of the FDL ratio using the best analysis of the most current and complete year of HH PPS data.

Outlier relationship to the HH Payment Study. CMS advises 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.

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 proposes to both rebase and revise the home health market basket for CY 2013 using CY 2010 Medicare cost report (MCR) data. 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. (For details on the rebasing and revising, see 77 FR 41555-41561.) The forecasted rate of growth for CY 2012, beginning January 1, 2012, for the proposed rebased and revised HH market basket is 2.5 percent, while the forecasted rate of growth for the current 2003-based HH market basket is 2.3 percent. (See Table 9 at 77 FR 41561.) The higher

growth rate for the 2010-based HHA market basket is attributable to the proposed wage and benefit blended price proxies and the relatively faster price growth for the Administration and General cost category. The revised wage and benefit blended index reflects a larger weight associated with health professional and technical occupations compared to the 2003-based index. The wage and benefit Employment Cost Indexes (ECIs) for hospital workers are 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 percent while the remaining non-labor-related share was 22.918 percent. In the proposed revised and rebased market basket, the labor-related share would be 78.535 percent. (The labor-related share includes wages and salaries and employee benefits, as well as allocated contract labor costs.) The proposed nonlabor-related share would be 21.465 percent. The increase in the labor-related share using the 2010-based HH market basket is primarily due to the increase in costs associated with contract labor.

Labor-Related Share of Current and Proposed Home Health Market Baskets		
Cost Category	**2003-Based Market Basket Weight**	**Proposed 2010-Based Market Basket Weight**
Wages and Salaries	64.484	66.325
Employee Benefits	12.598	12.210
Total Labor Related	77.082	78.535
Total Non-Labor Related	22.918	21.465
Table 10, 77 FR 41562.		

Proposed CY 2013 Market Basket Update for HHAs. For CY 2013, CMS proposes 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 is 2.5 percent. Consistent with the agency's historical practice of estimating market basket increases based on the best available data, CMS is proposing a market basket update of 2.5 percent for CY 2013. If more recent data are subsequently available (for example, a more recent estimate of the market basket), CMS proposes to use such data, if appropriate, to determine the CY 2013 annual update in the final rule.

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. Consistent with the statute, CMS advises that the CY 2013 market basket update of 2.5 percent must be reduced by 1 percentage point. Thus, the proposed CY 2013 home health payment update is 1.5 percent.

3. Home Health Quality Reporting Program (QRP)

The law provides that HH agencies that meet quality data reporting requirements are eligible for the full HH market basket percentage increase. HHAs that do not meet the reporting requirements are subject to a 2 percentage point reduction to the HH market basket increase. In addition, the Secretary is required to establish procedures for making quality data available to the public, ensuring though that the HH agency 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 proposes 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 allows for 12 full months of data collection and would provide CMS with the time to analyze and make any necessary payment adjustments to the payment rates for CY 2013. CMS proposes to continue this pattern for each subsequent year beyond CY 2013, considering OASIS assessments submitted in the time frame between July 1 of the calendar year two years prior to the calendar year of the Annual Payment Update (APU) effective date and July 1 of the calendar year one year prior to the calendar year of the APU effective date as fulfilling the OASIS portion of the quality reporting requirement for the subsequent APU.

(2) Acute Care Hospitalization Claims-Based measure. CMS has determined that claims data are a more robust source of data for accurately measuring acute care hospitalizations than other data sources. CMS thus proposes that the claims-based Acute Care Hospitalization measure replace the OASIS-based measure on Home Health Compare. The OASIS-based measure, however, will continue to be reported on the agency-specific Certification and Survey Provider Enhanced Reporting system (CASPER) reports. CMS advises that due to technical issues with Home Health Compare files, the reporting of both "Emergency Department Use Without Hospitalization" and "Acute Care Hospitalization" will be delayed until the technical issues are resolved. The OASIS-based Acute Care Hospitalization measure will continue to be made available to the public via Home Health Compare until it is replaced with the claims-based measure.

Home Health Care CAHPS Survey (HHCAHPS). CMS notes 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 41563-4.)

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 proposes 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).

HHCAHPS requirements for CY2014 and CY2015. CMS restates the reporting requirements that were included in the CY 2011 final rule:

> For the CY 2014 Annual Payment Update (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. No changes to this process are being proposed. CMS notes that HHAs have 30 days to send their reconsiderations to CMS and that CMS has and will continue to fully examine all HHA reconsiderations.

4. Home Health Wage Index

As in prior years, CMS will 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 will 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.

The labor-related share of the case mix adjusted 60-day episode rate for CY 2013 is 78.535 percent and the non-labor related share will be 21.465 percent.

5. Proposed CY 2013 Payment Update

National Standardized 60-Day Episode Rate

CMS is increasing the CY 2012 payment rate by 1.5 percent (the estimated CY 2012 HH market basket increase of 2.5 percent less 1.0 percentage point as mandated by the ACA) and then reducing the rates by 1.32 percent to adjust for the observed nominal change in case mix, resulting in the final CY 2013 urban standardized 60-day episode payment rate of $2,141.95 for HHAs that submit the required quality measures. See the table below for details (from Tables at 77 FR 41566-67).

CY 2013 National 60-Day Urban Episode Payment Amount Before Case-Mix Adjustment and Wage Adjustment		
Final CY 2012 Urban National Standardized 60-Day Episode Payment rate for HHAs that Do Submit Required Data	CY 2013 Urban National Standardized 60-Day Episode Payment rate for HHAs That Do Submit Required Data	CY 2013 Urban National Standardized 60-Day Episode Payment rate for HHAs that Do Not Submit Required Data
$2,138.52	$2,141.95	$2099.74

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

The 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.

Proposed 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	$51.90	$50.87
Medical Social Services	$183.67	$180.06
Occupational Therapy	$126.12	$123.64
Physical Therapy	$125.28	$122.81
Skilled Nursing Services	$114.57	$112.32
Speech Language Pathology Therapy	$136.13	$133.45
Table 13. 77 FR 41567		

CMS proposes that the LUPA add-on payment to HHAs that submit required quality data be updated by the proposed CY 2013 home health payment update of 1.5 percent. It proposes that the LUPA add-on payment to HHAs that do not submit the required quality data be updated by the proposed CY 2013 home health payment update (1.5 percent) minus 2 percentage points.

Proposed CY 2013 LUPA Add-On Amounts		
CY 2012 LUPA Add-On Payment Amount	**CY 2012 LUPA Add-On Payment Amount for HHAs That Submit Required Quality Data**	**CY 2012 LUPA Add-On Payment Amount for HHAs That Do Not Submit Required Quality Data**
$94.62	$96.04	$94.15
Table 14. 77 FR 41567		

Additional calculations are made to account for Nonroutine Medical Supplies (NRS) (see tables 15-18 of the proposed rule at 77FR 41568). CMS increases the CY 2012 NRS conversion factor ($53.28) by the proposed payment update of 1.5 percent, for a total of $54.08. Using that conversion factor for CY 2013, the payment amounts for the various severity levels are shown in Table 16. The different amounts for HHAs that do and do not submit the required quality data are shown in Tables 17 and 18.

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 19 through 23 at 77 FR 41569-70.)

D. Home Health Face-to-Face Encounter

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 has 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 proposes 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 encourages comment on these proposed changes**. CMS says that in addition to meeting the goals of the face-to-face encounter provision, this proposed policy change will 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 proposes 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 encourages comment on this proposed change.

E. Therapy Coverage and Reassessments

Therapy Coverage. 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 13th or 19th visit, assess the patient, and measure and document effectiveness of the therapy.

Two issues have been raised with these requirements. The first involves the timing of when the resumption of coverage occurs after a qualified therapist misses one of the required 13th/19th or at least once every 30 days reassessment visits. Currently, when a qualified therapist misses one of the required reassessment visits, once the therapist has completed the required reassessment, coverage resumes after this reassessment visit. Some agencies and therapists believe that the reassessment visit should be covered since therapy was also provided during that visit even though it was not timely. The second 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 has concerns that this requirement may be negatively impacting 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 proposes 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 expects that this will result in minimal changes to claims submissions but will monitor claims for unintended consequences, including possible up-coding associated with therapy-related home health resource groups (HHRGs) pre- and post-implementation. In addition, CMS proposes 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 encourages comment on these proposed changes.**

When Therapy Reassessment Visits are to be covered. Under current policy, if either a patient lives in a rural area, or documented circumstances outside the therapist's control prevent her or him from completing the reassessment visit at the 13th or 19th visit, this requirement can be met by the therapist having made the visit during the 11th or 12th visit for the required 13th visit or the 17th or 18th visit for the required 19th visit. CMS continues to receive questions regarding acceptable visit ranges for the required 13th and 19th reassessment visits. CMS also intends for similar flexibility to be applicable in cases where beneficiaries are receiving more than one type of therapy.

CMS is thus proposing 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. **CMS seeks comment on these proposed changes.**

Technical correction to G-Code description. CMS proposes to make a technical correction to terminology in G0158 so that the new description would include the terminology, "occupational therapy assistant," instead of the current "occupational therapist assistant" making it also consistent with §484.4.

F. Payment Reform: Home Health Study and Report

The ACA requires the Secretary to conduct a study on HHA costs of providing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and of treating beneficiaries with varying levels of severity of illness. CMS may also analyze methods to revise the current HH PPS to ensure access to care and better account for costs for these beneficiaries. The Report to Congress must be delivered no later than March 1, 2014.
As noted in the CY 2012 proposed rule (76 FR 41025), CMS awarded a contract in the fall of 2010 to perform exploratory work for the study. The contractor performed a literature review of HH PPS payment vulnerabilities and access issues, established and convened technical expert panels and open door forums to help define the vulnerable populations and to gain insight on access issues these populations may face, and performed preliminary analysis looking at resource costs versus Medicare reimbursement. In September 2011, CMS awarded a study contract to develop an analytic plan, perform detailed analysis, and if necessary, develop recommendations for changes to the HH PPS. CMS is in the preliminary stages of analyses; it will provide progress updates in future rulemaking and open door forums.

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

On April 17, 2012, HHS published a proposed rule relating to Administrative Simplification (77 FR 22950) in which CMS proposed, among other things, to delay, from October 1, 2013 to October 1, 2014, the compliance date for the ICD-10 diagnosis and procedure codes. CMS will include an update in the final rule and outline any impact on its ICD-10 transition plans as a result of the proposed change in ICD-10 compliance date.

Despite the compliance date change, CMS continues to work with the HH PPS Grouper maintenance contractor to revise the HH PPS Grouper to accommodate ICD-10-CM codes. If determined to be appropriate, CMS plans to publish a draft list of ICD-10-CM codes for the HH PPS Grouper by the summer of 2012 for industry review and comment. CMS 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 Web site in conjunction with the release of the draft grouper in April 2013. It also plans to update providers through the ICD-10 Home Health section of the CMS

Web site, the Home Health, Hospice and DME Open Door Forums, and provider outreach sessions for ICD-10.

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 is proposing 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; (2) 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. (See 77 FR 41573 for additional details of these proposals.)

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 reduction in their market basket update by 2 percentage points 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 respective 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

1. Quality Measures for Payment Year 2014

In the Hospice Wage Index for 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

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 proposes 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 is not extending the requirement that hospices provide a list of their patient care indicators. **CMS invites comment on the proposed selection of measures.**

2. Data Submission Requirements for Payment Year 2015

CMS advises that all hospice quality reporting periods subsequent to that for Payment Year FY 2014 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

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). **CMS seeks comments on whether all, some, any, or none of these measures should be considered for future rulemaking.**

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. 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. **CMS welcomes comments on the potential implementation of a hospice patient-level data item set in CY 2014.**

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 and **welcomes comments on the potential implementation of these measures and the projected timeframe for implementation.**

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. **Comment is requested on the succession of implementation of these two potential requirements.**

IV. Survey and Enforcement Requirements for Home Health Agencies

A. Background and Statutory Authority

The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) authorized the Secretary to change the manner in which CMS regulated and carried out enforcement actions with respect to HHAs participating in the Medicare program. The amendments mandated an outcome-oriented survey process for HHAs that would include "a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care.. . .” CMS responded by creating such a survey process for HHAs that included specific procedures to be followed, including visits to patients in their homes. CMS also defined in policies, although not in regulation, the different types of surveys to be used, including the standard, partial extended and extended surveys addressed in section 1891 of the Act. This proposed rule would codify these types of surveys in regulation.

The HHA Conditions of Participation (CoP) were originally issued in 1973, with revisions made in 1989 and 1991 to implement provisions of OBRA’87. Additional minor revisions to the CoP have been made since that time. Over the years, additional home-health-specific areas of focus for CMS have included adjustments to the HH PPS and OASIS. The CoPs apply to an HHA as an entity, as well as to the services furnished to each individual under the care of the HHA, unless the CoPs are specifically limited to Medicare/Medicaid beneficiaries, such as the OASIS requirements. 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.

On August 2, 1991, CMS published the Survey Requirements and Alternative Sanctions for Home Health Agencies proposed rule (56 FR 37054) that proposed to establish survey and enforcement requirements, as well as alternative sanctions for HHAs under section 1891 of the Act, implementing the OBRA '87 provisions. CMS explains that though it attempted to finalize the proposed rule numerous times since its publication on August 2, 1991, "sweeping changes in the law and other regulations, together with the demands of additional improvement efforts, impeded the promulgation of a final rule." CMS responded to an August 2008 Office of Inspector General (OIG) Report, "Deficiency History and Recertification of Medicare Home Health Agencies," that the 1991 proposed rule would require substantial revisions and republication to implement the alternative sanctions. Due to the length of time that has passed since the 1991 publication of the proposed rule, CMS is now publishing a new proposed rule, which would implement those survey and enforcement requirements, as well as establish alternative sanctions specified under §1891(f) of the SSA for HHAs.

B. Provisions of the Proposed Rule

1. Overview

CMS proposes 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 CoP. CMS also would amend certain sections of 42 CFR part 488, 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.

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

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 CoP. Proposed §488.705 would define certain terms that have been part of longstanding CMS policy but have not yet been codified in the regulations for HHAs.

Standard Surveys §488.710. 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.

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.

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.

Unannounced Surveys (§488.725). 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.

Survey frequency and content (§488.730). 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: 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.

Surveyor qualifications (§488.735). Surveys would have to 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.

Certification of Compliance or Noncompliance (§488.740). This section 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 CoP.

Informal Dispute Resolution (IDR) §488.745. 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.

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

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 proposes to set out the statutory basis for the new subsection at proposed §488.800, providing for termination of HHAs that fail to comply with CoP. It would also provide for ensuring that the procedures with respect to the conditions under which each of the alternative sanctions developed by the Secretary shall be designed to minimize the time between identification of deficiencies and imposition of these sanctions, including incrementally more severe fines for repeated or uncorrected deficiencies. The section also states 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.

CMS proposes to add §488.805 to define frequently used terms. Although section 1891 of the SSA uses the term "intermediate sanctions," for consistency with other enforcement rules, this proposed rule uses "alternative sanctions" to have the same meaning.

General provisions (§488.810). CMS proposes that when CMS chooses to apply one or more sanctions specified in §488.820, they be applied on the basis of noncompliance with CoP 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 is 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.

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.

Factors to be considered in selecting sanctions (§488.815). CMS would 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 would apply its statutory authority to provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. (These terms are defined.)

Available sanctions (§488.820). CMS proposes that in addition to termination of the provider agreement, the following alternative sanctions be available: 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.

Action when deficiencies pose immediate jeopardy (§488.825). CMS proposes 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.

Action when deficiencies are at the condition-level but do not pose immediate jeopardy (§488.830). CMS is interested in providing incentives for HHAs to achieve and maintain full compliance with program requirements before termination becomes necessary and reflects this in the details of this part of the proposed rule:

- If the HHA is no longer in compliance with the CoP, 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 CoP 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.

Temporary management (§488.835). CMS proposes 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 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 a 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).

Suspension of payment for all new admissions and new payment episodes (§488.840). 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" is

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 is 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.

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. CMS says that 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.

Civil Money Penalties (CMPs) (§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 proposes in this section both “per day” and “per instance” CMPs. A “per instance” CMP may range from $1,000 to $10,000. 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 conditions of participation and to ensure patient health and safety.

CMS further proposes 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 are 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.

For illustrative purposes, Table 24 of the NPRM (77 FR 41583) shows the relationship between the existing survey protocols and proposed ranges of CMP imposition. For each level of seriousness (e.g. immediate jeopardy), a specific CMS fine range/amount is displayed.

CMS would 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 77 FR 41583). 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.

CMS also proposes 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 CoP 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 are also proposed (see 77 FR 41584).

Offsets. CMS proposes that the amount of any penalty be deducted (offset) from any sum CMS or the State Medicaid Agency owed to the HHA. Interest would be assessed on the unpaid balance of the penalty beginning on the due date 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 is described (see 77 FR 41584).

Disbursement of recovered CMP funds. CMS proposes 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 percent of the CMP amounts recovered would be deposited as miscellaneous receipts to the U.S. Department of the Treasury and approximately 37 percent would be returned to the state Medicaid Agency to improve the quality of care for those who need home-based care. Beginning one year after these rules are finalized and become effective, these proportions would be updated annually based on the most recent 3 year period for which CMS determined that the Medicare and Medicaid expenditure data were essentially complete.

Costs of home health surveys. Consistent with the proposed disbursement to States of a portion of federally imposed CMP amounts collected, CMS proposes to provide that state Medicaid programs 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

projects the initial cost to the Medicaid program to be approximately 37 percent of the cost of surveys for dually-certified programs. Comment is requested on this new proposed requirement for State Medicaid programs and the methodology for calculating the state share of both survey costs and CMP disbursement.

Directed plan of correction (§488.850). CMS proposes a directed plan of correction as an available sanction. This sanction is a part of the current nursing home alternative sanction procedures and has been an effective tool to encourage correction of deficient practices. Specifically, CMS would be able to impose a such a correction on an HHA which is out of compliance with the CoP. 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.

Directed in-service training (§488.855). CMS proposes 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.

Continuation of payments to HHAs with deficiencies. The law authorizes the Secretary to continue Medicare payments to HHAs not in compliance with the CoP 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 proposes 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 CoP 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 CoP within 6 months of the last day of the survey, CMS would terminate the provider agreement.

Termination of provider agreement (§488.865). 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) met 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.

C. Provider Agreements and Supplier Approval

CMS proposes 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.

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. **CMS asks for comments on additional public notices.** CMS is 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 seeks comments on the proposed definition of "per instance" of noncompliance when imposing a CMP sanction.**

V. Collection of Information Requirements

CMS describes in this section the information reporting requirements associated with the proposed rules related to HHAs and hospice quality reporting and finds that they 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 77 FR 41586-87.)

VI. Regulatory Impact Analysis

CMS advises that this proposed 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 $20 million in CY 2013 savings. This amount reflects the distributional effects of an updated wage index ($70 million decrease) the +1.5 percent HH payment update ($300 million increase), and the -1.32 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($250 million decrease). The $20 million in savings is reflected in the first row of column 3 of Table 25 as a 0.1 percent decrease in expenditures when comparing the current CY 2012 HH PPS to the proposed CY 2013 HH PPS. (For the CMS discussion of alternative policies, see 77 FR 41590. **Comments are solicited on the alternatives.**)

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 0.11 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. In addition, changes to the Medicare program may continue to be made as a result of the ACA, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs. (See Table 25 at 77 FR 41589-90 for specific impacts projected by facility type and area of the country.)

Survey and Enforcement Requirements for Home Health Agencies

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 a onetime $2 million expense to modify the survey information collection system (ASPEN) to monitor CMPs. There would also be additional, annual operating expenses of $335,972 associated with maintaining the system, training surveyors and troubleshooting issues.. CMS notes that the provisions in this proposed rule related to survey protocols have already been incorporated into long standing CMS survey policy, implemented in the years after 1987 and most recently revised in 2011. CMS projects that aggregate Medicare and Medicaid home health survey costs in FY 2013 and FY 2014 would be $39.9 million and $45.7 million, respectively. Assuming a standard State Medicaid obligation of 37 percent of the total, the Medicaid share would amount to $14.7 million and $16.9 million, respectively. The cost of surveys is treated as a Medicaid administrative cost, reimbursable at the professional staff rate of 75 percent. At this rate the net State Medicaid costs incurred in FYs 2013 and 2014 would be approximately $3.7 million and $4.2 respectively (that is, 25 percent of $14.7 million and $16.9 million), spread out across all States and territories. CMS also notes benefits: that HHAs will be provided incentives to maintain or regain compliance with the Home Health CoP through measures other than termination (see 77 FR 41590-1).

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.