DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 418, 424, 484, and 489

[CMS–1510–F]

RIN 0938–AP88

Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices

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

ACTION: Final rule.

SUMMARY: This final rule sets forth an update to the Home Health Prospective Payment System (HH PPS) rates, including: the national standardized 60-day episode rates, the national per-visit rates, the nonroutine medical supply (NRS) conversion factors, and the low utilization payment amount (LUPA) add-on payment amounts, under the Medicare prospective payment system for HHAs effective January 1, 2011. This rule also updates the wage index used under the HH PPS and, in accordance with the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), updates the HH PPS outlier policy. In addition, this rule revises the home health agency (HHA) capitalization requirements. This rule further adds clarifying language to the "skilled services" section. The rule finalizes a 3.79 percent reduction to rates for CY 2011 to account for changes in case-mix, which are unrelated to real changes in patient acuity. Finally, this rule incorporates new legislative requirements regarding face-to-face encounters with providers related to home health and hospice care.

DATES: *Effective Date:* These regulations are effective on January 1, 2011.

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Table of Contents

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Background

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

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

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

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

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

Section 1895(b)(5) of the Act, as amended by section 3131 of the Patient Protection and Affordable Care Act of 2010 (The Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010) gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 3131(b) of the Affordable Care Act revised section 1895(b)(5) of the Act so that the standard payment amount is reduced by 5 percent and the total outlier payments in a given fiscal year (FY) or year may not exceed 2.5 percent of total payments projected or estimated. The provision also makes permanent a 10 percent agency level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the

1997 HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted on October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113, enacted on November 29, 1999). The requirements include the implementation of an HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

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

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. The amended section 421(a) of the MMA now requires, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016, that the Secretary increase by 3 percent the payment amount otherwise made under section 1895 of the Act.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS based on a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for nonroutine medical supplies (NRS) is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section III.C.4.e. of this final rule). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument.

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

C. Updates to the HH PPS

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HHAs for CY 2008.

That rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. The case-mix represented the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 12.78 percent increase in case-mix to evaluate if any portion of the increase was associated with a change in the actual clinical condition of HH patients. We examined data on demographics, family severity, and non-HH Part A Medicare expenditure data to predict the average case-mix weight for 2005. As a result of the subsequent detailed analysis, we recognized that an 11.75 percent increase in case-mix was due to changes in coding practices and documentation, and not to treatment of more resource-intensive patients.

To account for the changes in case-mix that were not related to an underlying change in patient health status, CMS implemented a reduction over 4 years in the national standardized 60-day episode payment rates and the NRS conversion factor. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. We indicated that we would continue to monitor for any further increase in case-mix that was not related to a change in patient status, and would adjust the percentage reductions and/or implement further case-mix change adjustments in the future.

For CY 2010, we published a final rule in the November 10, 2009 **Federal Register** (74 FR 58077) (hereinafter referred to as the CY 2010 HH PPS final rule) that sets forth the update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HH services.

D. Comments Received

In response to the publication of the CY 2011 HH PPS proposed rule, we received approximately 500 items of correspondence from the public. We received numerous comments from various trade associations and major health-related organizations. Comments also originated from HHAs, hospitals, other providers, suppliers, practitioners, advocacy groups, consulting firms, and private citizens. The following discussion, arranged by subject area, includes our responses to the comments, and where appropriate, a brief summary as to whether or not we are implementing the proposed provision or some variation thereof.

General (Miscellaneous)

Comment: A commenter stated that multiple policy changes and payment reductions have led to the industry's inability to apply "cause-and-effect" analysis when HH care access becomes critical. The commenter recommends applying changes one at a time and phasing them in to allow time to determine the impact of those individual changes. Another commenter stated that as an HHA owner, she is

willing to accept cuts to the Medicare HH benefit but that the cuts need to be incremental so agencies have the time and the resources to implement adjustments in response to payment changes. In addition, there is the growing concern of the "unknown" costs associated with implementation of the Affordable Care Act. Another commenter stated that the health insurance costs for their employees have skyrocketed over the past 3 years, and that in conjunction with these cuts, it hinders their ability to hire staff.

Response: We have, in fact, been phasing in the reductions to the HH PPS rates for the increase in nominal case-mix. As a result of the CY 2008 final rule, we have reduced HH PPS rates by 2.75 percent for 2008, 2009, and 2010 to account for the increase in nominal case-mix, that is an increase in case-mix not due to actual changes in patient characteristics. However, there still exists significant nominal case-mix increase in the payment system that has not yet been addressed. Consequently, we believe that the case-mix adjustments continue to be necessary in order to address the residual increase in the nominal change in case-mix that has not yet been accounted for in the payment system. As such, we are moving forward with phasing in our case-mix reductions and will be applying a 3.79 percent reduction to the HH PPS rates in CY 2011 (as discussed in the July 23, 2010 proposed rule). In response to comments that we received on our case-mix model and its measurement of real case-mix, we will further study the concerns raised and are not finalizing the proposed 3.79 percent reduction to the HH PPS rates for CY 2012 at this time. Therefore, in addition to our continuous monitoring of nominal case-mix increase, we plan to perform a review of our case-mix and NRS models, and address any reductions to the CY 2012 HH PPS payments in next year's rulemaking. The other policy changes and reductions addressed in this rule (that is, outlier provisions and reductions to the market basket update) were mandated by the Affordable Care Act. We are uncertain of the meaning of "unknown" costs as referenced by the commenter and therefore are unable to address the particular concern.

Comment: A commenter stated that he receives calls from providers who are confused with the language that is used by CMS in determining billing requirements. He believes the proposed changes are a step in the right direction.

Response: We appreciate the comment and will continue to work towards providing the industry/public with clear policies, instructions, and guidance as they relate to our payment policies.

Comment: With the increased use of technology and telehealth, funds should be made available to HHAs to include such monitoring to allow patients and their families to be more proactive in the management of their illnesses and to reduce ER visits, primary care physician appointments and hospital stays. Home Health is the area to fund, not to cut, and that medical spending in other areas should be reduced.

Response: We are not opposed to improvements in technology, or the use of telehealth in the HH setting and certainly do not discourage the use of these advances in medicine. However, under section 1895(e) of the Act, telehealth services cannot substitute for in-person HH services ordered as part of a plan of care. However, telehealth can be used to supplement traditional HH services.

Section 1895(b)(3)(B) of the Act dictates how HH PPS rates are to be updated annually, and section 3131(a) of the Affordable Care Act, amending this provision, requires the Secretary to rebase HH payments beginning in 2014. At that time, more up-to-date costs will be used to rebase payments to HHAs.

Comment: A commenter stated that the impact analysis in the proposed rule is useless in that the analysis simply quantifies the percentage cut in rates on a geographic basis. Further, the impact analysis offers little substantive understanding of the individual cost impact of such proposed provisions as the physician face-to-face encounter requirement, the revisions to therapy assessment, coverage and documentation standards, coding change proposals, and CAHPS compliance. The estimated costs are vastly understated because they do not include the sizeable administrative expenses that HHAs will incur to implement any of the changes beyond the cost of some of the form revisions.

A valid and useful impact analysis starts with an understanding of the results of the combination of rate cuts and cost increases that the proposed policies will bring to HHAs. The commenter further asserts that once these results are fairly and accurately determined, the impact analysis must begin with the highest of priority concerns—impact on access to care—as that is the central purpose of Medicare. Second, the commenter believes that the impact analysis should continue with an evaluation of the effect of the proposed policies on total spending for the Medicare program, not just the effect on HH services spending.

The commenter provided the example that if the analysis of the proposed policies' impact on access to care shows that thousands of Medicare beneficiaries would no longer have HH care available or that provision of HH services would be significantly delayed, Medicare spending would rise as a result of a shift to higher cost care such as skilled nursing facility services or extended inpatient stays.

The commenter also proposed that the impact analysis should evaluate the impact of the proposed policies on another stakeholder—HHAs as businesses. Such evaluation should start with the ongoing viability of the individual businesses and the industry as a whole. Among the many elements that should be reviewed is whether the business will be paid less than the cost of the delivery of care. Another element is the workforce impact—will health care workers take their talents to other care sectors because of reductions in compensation and benefits. Access to capital is also an important factor to evaluate. If the proposed rule changes restrict access to capital, there may be reduced use of efficiency-related technologies or business expansions to achieve economies of scale. Lack of access to capital could also mean an inability to meet ongoing payroll obligations because of cash flow problems.

The commenter also claimed there is another flaw in the CMS impact analysis, which is its limited review to a single year. This is particularly concerning to the commenter because the proposed rule extends rate cuts into a second year. An impact analysis that does not evaluate the impact of cuts in payment rates for both of the years as proposed is invalid and in violation of CMS obligations under the Regulatory Flexibility Act.

The commenter strongly recommends that CMS conduct a thorough and valid impact analysis, consistent with the concerns referenced above. Another commenter states that in the proposed rule CMS concluded that the proposed rule would not have a significant impact on a substantial number of small entities. Section 605 of the Regulatory Flexibility Act (RFA) requires that if the regulatory agency certifies that the rule will not have a significant impact on a substantial number of small businesses, it must include a statement providing the factual basis supporting the certification. The commenter suggests that CMS failed to provide an adequate factual basis for its certification that there would be no significant impact. In fact, there is no language in the RFA section of the proposed rule that

discloses the reasons why CMS concluded that there would be no substantial impact on small HHAs. CMS should at a minimum have provided the public with information on the number of HHAs and other health care entities likely to be affected by the rule. Further, CMS has guidelines (usually based on small business revenues) in place that the agency uses to determine whether a rule will have a significant impact on a substantial number of small entities. CMS failed to discuss how the impacts of this rule fall within those guidelines. Such a discussion is vital for the purposes of transparency, as affected small entities can use this information to provide CMS with economic impact information on the rule's projected impact on their business. Based on the public input, the commenter asserts that CMS could determine the validity of their decision to certify the rule in the publication of the final regulation.

The commenter is concerned that while CMS has certified that the rule will not have a significant impact, the affected HHAs still believe that the regulation will result in a significant burden on their businesses. The commenter believes that there is merit in bringing these small business concerns to the attention of CMS in the hope that they will add to the transparency of the RFA contained in the final rule.

Response: The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities for that year. As such, there is no requirement under the RFA to provide impacts for any year(s) beyond that which the rule is updating the rates. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any 1 year. For purposes of the RFA, approximately 95 percent of HHAs are considered small businesses according to the Small Business Administration's size standards, with total revenues of $13.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. As such, this rule is estimated to have an overall negative effect upon small entities (see section IV.B. of this final rule, "Anticipated Effects", for supporting analysis).

The last section of Table 19 shows the percentage change in payments by agency size, as determined by the number of first episodes. The agency size categories, for this rule, are based on the number of first episodes in a random 20 percent beneficiary sample of CY 2008 claims data. Initial episodes, under the HH PPS, are defined as the first episode in a series of adjacent episodes (contiguous episodes that are separated by no more than a 60-day period between episodes) for a given beneficiary. Initial, or first, episodes are a good estimate of agency size, because this method approximates the number of admissions experienced by the agency based on approximately one-fifth of the total annual data. The size categories were set to have roughly equal numbers of agencies, except that the highest category has somewhat more agencies because added detail amongst the large size category was not needed.

Because our model does not have the data to account for the "total" revenue of an HHA, in the proposed rule, and again in this final rule, we have used the number of first episodes as a proxy for agency size. As such, using the facility size categories (based on the number of first episodes), the impact table shows that the difference in impact between smaller and larger HHAs is small and within a 0.05 percentage point range. In fact, smaller agencies have a smaller reduction and fare slightly better than larger agencies represented by the "200 or more first episodes" category.

In an effort to better demonstrate the impact on small HHAs, as it relates to total revenue, we supplemented our impact analysis by linking to Medicare cost report data, which has total revenues for HHAs. Using total revenues and the $13.5 million threshold of the RFA, we categorized an HHA as being either small or large. To perform this analysis, we were able to match approximately 72 percent of the cost report data to our model. For the remainder of the agencies in the model, we proxy for large agencies as those agencies with at least 750 first episodes. This results in approximately 95 percent of agencies being classified as small and 5 percent of agencies being large, which is reflective of what our cost report files show us. This analysis provides similar results to the one using first episodes as a measure of an agency's size in that small HHAs fare slightly better, −4.84 percent impact, than do large HHAs, which are estimated to experience a −5.01 percent (see section IV.B. of this final rule, "Anticipated Effects", for supporting analysis).

In a separate, supplemental analysis, as merely an indicator of possible access to care issues, we looked at estimated margins of HHAs, by county, and the estimated effect that the provisions of this rule might have on HHAs. In particular, we look to identify counties that might not be served by at least one HHA with a positive margin as a result of the finalized policies of this rule. The analysis demonstrate that occurrence of such counties is very infrequent; thus, we do not believe that access to care is an issue (see section IV.B. of this final rule, "Anticipated Effects", for supporting analysis). Given the profit margins of HHAs that we and MedPAC are seeing in our analyses, we believe that the reductions of this final rule can be absorbed by the majority of HHAs, and that access to care will not be compromised. However, we will continue to monitor the situation to identify any unintended consequences of our policies in this final rule.

Comments Regarding Access to Care

Comment: A commenter stated that additional regulatory responsibilities of oversight, documentation, education, choosing survey vendors, etc., would result in increased costs to HHAs. There is an inherent risk for decreased quality of care and volume of services provided by HHAs. It is possible that HHAs may become more selective in their acceptance of medically difficult patients who are likely to utilize more services.

Response: We assume that the commenter is referring to the therapy provisions of this rule. We believe that our clarifications to our therapy coverage requirements do not constitute additional responsibilities, but rather clarify the existing responsibilities of the qualified therapist and the HHA. Similarly, we are clarifying the existing supervision/oversight requirements of qualified therapists in the HH setting. We are also clarifying our coverage requirements for education of the patient and/or family members, and our documentation requirements. We do not consider any of these clarifications to be beyond the current responsibilities of an HHA.

We are, as part of this final rule, requiring qualified therapists to perform the needed therapy service, assess patients and measure and document therapy effectiveness at what we consider key points of the episode. We believe that all HH patients who need therapy services would benefit from those services being delivered by a qualified therapist, instead of an assistant, at key points in the course of treatment. We will continue to monitor for unintended consequences of the provisions of this final rule.

Comment: Several commenters stated that the payment reductions would result in decreased access to care and force HHAs out of business. The

commenters assert that patients who are moved from acute care facilities to their homes and have major medical problems would not be able to get HH services for their illnesses. These proposed changes would not only endanger access to care but also impede efforts to transition patients to the home and cripple essential community HHAs. Several commenters stated that HH patients would be forced into costly institutional care and increase Medicare spending. Another commenter stated that if these proposed cuts were implemented, many senior citizens who have paid taxes in to the Medicare system for years would be forced to go into assisted living facilities and nursing homes or simply not receive the healthcare they deserve. In addition, their quality of life would be compromised.

Response: As discussed in a previous response to a comment, in a separate analysis in the regulatory impact section of this rule, we looked at margins of HHAs, by county, and the estimated effect that the provisions of this rule would have on HHAs. In particular, we studied the number of counties that would not be served by at least one HHA with a positive margin. Our analysis concluded that there were few counties in which no HHAs had positive margins; therefore, we do not believe that access to care will be adversely affected by these case-mix adjustments. Given the data on profit margins that we and MedPAC saw in our analyses, we believe that the reimbursement rate reductions set forth in this final rule can be absorbed by the majority of HHAs, and that access to care will not be compromised.

II. Provisions of the Proposed Rule and Response to Comments

A. Case-Mix Measurement

As stated in the proposed rule published on July 23, 2010, analysis of HH PPS claims shows total average case-mix grew at a rate of about 1 percent each year from 2000 to 2007, with 4 percent growth in 2008. Based on our analysis of the proportion of total case-mix change due to changes in real case-mix severity of the HH user population, the total amount of case-mix growth unrelated to real changes in patient severity (nominal case-mix) is 17.45 percent between 2000 and 2008. In each of the years 2008, 2009, and 2010, we reduced payment rates by 2.75 percent as recoupment for nominal case-mix change. A payment-rate reduction of 7.43 percent would be needed to account for the outstanding amount of nominal case-mix change we intend to recoup based on the real case-mix change analysis updated through 2008. In the proposed rule, we proposed to increase the planned 2.71 percent reduction in CY 2011 to 3.79 percent, and to make another 3.79 percent reduction in CY 2012. Doing so would enable us to account for the 7.43 percent nominal case-mix residual, while minimizing access to care risks. Iteratively implementing the case-mix reduction over two years gives HH providers more time to adjust to the intended reduction of 7.43 percent than would be the case were we to account for the residual in a single year.

For a complete description of the proposed case-mix refinements model and the underlying research, we refer readers to the CY 2011 HH PPS proposed rule (75 FR 43238 through 43244) published in the July 23, 2010, **Federal Register**.

Comment: Commenters stated that we should suspend or drop case-mix reductions because the proposal is based on the assumption that agencies intentionally gamed the system.

Response: As we have stated in previous regulations, changes and improvements in coding are important in bringing about nominal coding change. We believe nominal coding change results mostly from changed coding practices, including improved understanding of the ICD–9 coding system, more comprehensive coding, changes in the interpretation of various items on the OASIS and in formal OASIS definitions, and other evolving measurement issues. Our view of the causes of nominal coding change does not emphasize the idea that HHAs in general gamed the system. However, since our goal is to pay increased costs associated with changes in patient severity, and nominal coding change does not necessarily demonstrate that underlying changes in patient severity occurred, we believe it is necessary to recoup overpayments due to nominal coding change.

Comment: Commenters stated that all of the HHAs are being penalized for the corrupt actions of a few HHAs. Many commenters indicated that their agency had case-mix weights below the national average. Commenters stated that nominal case-mix change reductions should be limited to certain types of agencies (for example, those with high average case-mix index (CMI) or large weight increases or for-profit providers) or that CMS should implement different payment reductions by state or by geographical region, suggesting that their region has a lower nominal case-mix change than the national average. Other commenters recommended that reductions be proportional to an individual agency's CMI. For example, some commenters suggested that payment reductions be applied to those HHAs with an average case-mix above 1.20. Commenters stated that we should not implement payment reductions to all HHAs merely because that policy is easier to implement.

Response: For a variety of reasons, as we have noted in previous regulations, we have not proposed targeted reductions for nominal case-mix change. We have not conducted analysis of how and whether individual agencies' coding practices have changed over time because this is not feasible. One reason is that many agencies have small patient populations, which would make it practically impossible to measure nominal case-mix change reliably. Another reason is that we believe changes and improvements in coding have been widespread, so that such targeting would likely not separate agencies clearly into high and low coding-change groups.

Table 1A shows average case-mix by type of agency in 2000 and 2008. All types of agencies, regardless of region or profit status or size or affiliation, have substantial increases in their average case-mix. While for-profit agencies' case-mix grew approximately 19 percent, the case-mix average for non-profit agencies also grew considerably (16.6 percent). Case-mix grew just over 19.5 percent for freestanding agencies while case-mix for facility-based agencies grew just short of 15 percent. For rural agencies, case-mix grew almost 16 percent, while case-mix for urban agencies grew just under 19 percent. Rural agencies will receive an additional 3 percent rural add-on to their payments, which will help offset the case-mix reductions. It should be noted that the agency groups start from different base year values, but in general the percentage change in case-mix is roughly similar across these groups, with the possible exception of the Midwest, for which the percentage change is somewhat higher than the other changes—about 23 percent. No group could be said to have trivial case-mix change. Therefore, we believe our proposal to make across the board payment reductions is consistent with the data, and making distinctions by type of agency would be inappropriate.

TABLE 1A—ESTIMATES OF CASE-MIX CHANGE BY PROVIDER TYPE
[2000–2008]

	Actual case-mix		Case-mix change	
	2000 (IPS period)	2008	Total	Percentage
Overall				
All Agencies	1.0959	1.3085	0.2126	19.4
Ownership Type				
Non-profit	1.0840	1.2641	0.1801	16.6
Government	1.0672	1.2291	0.1619	15.2
For-profit	1.1202	1.3332	0.2130	19.0
Agency Type				
Facility-based	1.0834	1.2433	0.1599	14.8
Freestanding	1.1035	1.3200	0.2165	19.6
Region				
North	1.0422	1.2459	0.2037	19.6
South	1.1251	1.337	0.2118	18.8
Midwest	1.0865	1.3431	0.2566	23.6
West	1.0956	1.2648	0.1692	15.5
Facility Size (Number of 1st Episodes)				
< 99 episodes	1.0898	1.2499	0.1602	14.7
100 or more	1.1057	1.3266	0.2209	20.0
Urban/Rural				
Urban	1.1097	1.3184	0.2087	18.8
Rural	1.0478	1.2136	0.1657	15.8

Although we have stated in past regulations that a targeted system would be administratively burdensome, the reasons we have just presented go beyond administrative complexity. Certain comments seem to assume that the level of case-mix can precisely identify those agencies practicing abusive coding. We do not agree with the comments, which seem to assume that agency-specific case-mix levels can precisely differentiate agencies practicing abusive coding from others. System wide, case-mix levels have risen over time while patient characteristics data indicate little change in patient severity over time. That is, the main problem is the amount of change in the billed case-mix weights not attributable to underlying changes in actual patient severity. Moreover, we believe that a policy of varying payment levels according to regional differences in nominal case-mix change would be perceived as inequitable by beneficiaries. That is, beneficiaries who might have access only to agencies subject to larger payment reductions might believe Medicare's policies disadvantage them unfairly.

Comment: Commenters stated that we should suspend or drop case-mix adjustments because they will cause financial distress/bankruptcy among agencies, particularly "safety-net" agencies that take patients other agencies reject. Commenters further stated that the proposed payment reductions will cause "safety net" providers to have a "negative operating margin" and/or cause not-for-profit agencies to go out of business.

Response: Our analysis of the potential effect of the 2011 payment rate reductions suggests that while negative-margin agencies may increase in number, almost all such agencies are located in counties with other agencies predicted to have positive margins. We also note that predicting the size of the increase in negative-margin agencies is difficult to do because many agencies may find ways to cut costs or increase revenues so that margins do not deteriorate. Identifying the agencies that commenters call "safety-net" agencies is not feasible with our administrative data, so we cannot provide any evidence either to support or refute assertions that safety-net agencies are at greatest risk. Our analysis of margins of not-for-profit agencies shows that they tend to have lower margins than for-profit agencies. However, we do not agree that not-for-profit agencies will necessarily be more likely to exit the HH business than a for-profit agency. We believe the business decision is a complex one with many considerations, such as the organization's mission, the availability of alternate sources of funding, and whether or not the organization is embedded in a larger one. These influential factors are not necessarily associated with the non-profit or for-profit status of an agency, and therefore, we cannot accurately predict the business decision of an agency based solely on their status.

Comment: Commenters stated that we should suspend or drop case-mix adjustments because access would be reduced, particularly among hard-to-place patients. Commenters predicted that the payment reductions would have a "destabilizing effect" on HHAs and negatively impact patient access to HH care.

Response: MedPac has previously recommended to the Congress that HH rates be reduced by 5 percent. (MedPac, *Report to Congress: Medicare Payment*

Policy, March 2009). We believe HH industry margins are sufficient to support a rate reduction of that size. For example, MedPac projected 2011 margins would remain high, at 13.7 percent (assuming the previously planned rate reduction of −2.71 percent in 2011). MedPac also reported that the number of agencies continues to grow, reaching in excess of 10,400 in 2009. This is a 50 percent increase since 2002, although growth in new agencies has been highly uneven geographically. Notably, access to care was sufficient in 2001, when the number of agencies nationally was much lower than it is today (Office of the Inspector General, *Access to Home Health Care after Hospital Discharge,* July 2001, and Office of the Inspector General, *Medicare Home Health Care Community Beneficiaries,* October 2001). Our analysis of cost reports submitted by the end of 2008 indicates that 99 percent of beneficiaries are in counties served by at least two agencies, with more than half of beneficiaries in counties served by at least 11 agencies. Predictions about the number of bankruptcies and effects on access are highly uncertain. Furthermore, we have no indications that payment reductions implemented since 2008 have led to access problems among beneficiaries. During the succeeding period, the total number of agencies has continued to grow, which is indirect evidence that access levels have not deteriorated. We intend to request that the Office of the Inspector General resume investigations of the access impacts of payment reductions. We will continue to monitor access to care in order to identify any unintended consequences of our policies in this final rule. We emphasize that the justification for the nominal case-mix payment reductions is not HHA margins but rather is the increase in billed case-mix weights, which our analysis indicates, is unrelated to changes in underlying patient health characteristics.

Comment: Commenters suggested that we provide funding to HHAs that admit patients that other agencies avoid.

Response: We have received comments of this nature over the years. We are unable to definitively characterize such a categorization of HHAs using administrative data. While we welcome information as to the characteristics and identity of such agencies, so that we can study their performance, we would also need to study carefully the implications of making such distinctions on a permanent basis in our payment system. We expect many issues would arise. In future rulemaking we will solicit comment on the various challenges that might arise in administering payments differently to what some commenters called "full access organizations" and potentially other categories of agencies that might be capable of mitigating access problems, should they arise.

Comment: Some commenters suggested that CMS focus its efforts on the study, which will assess possible changes to the HH PPS in order to ensure access to care.

Response: Section 3131(d) of the Affordable Care Act mandates that the Secretary conduct a study to evaluate costs related to providing care to low-income beneficiaries, beneficiaries in medically underserved areas, and beneficiaries with varying levels of severity of illness. The section directs the study to be focused on ensuring access to care for patients with characteristics associated with especially high costs. We are preparing to launch the mandated study in FY 2011.

Comment: Commenters stated that CMS should suspend or drop nominal case-mix change reductions because those payment reductions are contrary to congressional intent in the Affordable Care Act, which implemented payment reductions on a separate basis. Furthermore, commenters stated that the 3.79 percent case-mix payment reduction should count as the "5 percent cut mandated by the [Affordable Care Act]" and the proposed payment decreases should not be implemented in addition to the Affordable Care Act-mandated payment reductions.

Response: Section 3401(e) of the Affordable Care Act mandated a market basket reduction and future productivity adjustments. In the Affordable Care Act, Congress did not make any changes to the pre-existing provision authorizing CMS to reduce payment rates in response to nominal case-mix change. Nor did the Congress authorize a substitution of the case-mix payment reduction for the Affordable Care Act's five percent payment reduction related to outlier payments (Section 3131(b) of the Affordable Care Act). Therefore, the reductions for nominal case-mix changes comply with current law.

Comment: Commenters stated that CMS should suspend or drop case-mix reductions because CMS should give specific proposals such as therapy documentation and comorbidity case-mix weight changes time to work.

Response: Our proposals are intended to recoup excess outlays that have already been made through 2008, outlays that were not justified by changes in patient severity. Going forward, beginning with 2011, we would expect to see a moderation of nominal case-mix growth because of the proposals mentioned by the commenters. Such moderation would decrease recoupment, if any, proposed in the future.

Comment: A commenter stated that the need for payment reductions in HH care is "consistent with the experience of coding changes in other payment systems." However, the methodology "used to establish the reduction percentage" in the inpatient system was flawed and, therefore, the methodology used to establish the payment reduction for HH is probably flawed as well.

Response: The payment systems, institutional conditions, data resources, case-mix assignment procedures, and many other aspects differ across care settings. Therefore, methodologies must each be judged on their own individual merits. We have explained and justified the methodology in this and in previous regulations cited elsewhere in this preamble.

Comment: We received a comment recommending that we focus the application of the case-mix change adjustment only to visits beyond the 13th day by changing the OASIS scoring and rate calculation for the extended cases rather than reducing the base rate and affecting all visits as a result.

Response: We are unsure of the specific change recommended in this comment, but we would be concerned that any approach to rate reduction based on the length of time in treatment within the 60-day episode would affect fundamental assumptions of the HH PPS system. Most notably, the system assumes that the amount of resources within the 60-day period, rather than the timing of their expenditure within that period, is the appropriate variable use to determine payments in the case-mix-adjusted payment system.

Comment: One commenter stated that a recent study that used data from a nationally representative survey (the Medical Expenditures Panel Survey—MEPS) found a change in real case-mix between 2000 and 2007.

Response: We thank the commenter for the comments. However, we note that the MEPs analysis appears to be based on all Medicare beneficiaries, not just the subset of HH patients. Home health users are less than 10 percent of the fee for service enrolled Medicare population, so it is not certain that the MEPS study of the entire Medicare population is relevant to the question of worsening health status of HH users.

Comment: Commenters stated that CMS should suspend or drop case-mix reductions because the data used to determine the reductions do not

recognize real increases in severity due to earlier and sicker hospital discharges.

Response: While we recognize that average lengths of stay in acute care are in decline, our analysis shows that agencies are, in fact, caring for fewer, not more, post-acute patients. Since 2001, the average length of stay in acute care preceding HH has declined by about one day, from 7 days to 6 days. However, agencies are caring for fewer highly acute patients in their caseloads. The proportion of non-LUPA episodes in which the patient went from acute care directly to HH within 14 days of acute hospital discharge declined substantially between 2001 and 2008, from 32 percent to 23 percent. In addition, the median acute hospital length of stay for these non-LUPA episodes with a 14-day lookback period has remained unchanged at 5 days since 2002 (see Table 1B, 50th percentile). Since 2005, the distribution has been stable, except for a 1-day shortening of lengths of stay at the 5th, 80th, and 99th percentiles. We believe the declining prevalence of recent acute discharges is due in part to more patients incurring recertifications after admission to HH care, and due to more patients entering care from the community. The shortening lengths of stay at the right tail (high percentiles) of the distribution may reflect changing utilization of long-term-care hospitals during recent years. The conclusion we draw from these data is that while patients on average have shorter hospital stays, agencies are also facing a smaller proportion of HH episodes in which the patient has been acutely ill in the very recent past. Also, the detailed data on the distribution of stay lengths suggest that for the most part lengths of stay for such patients remained stable through 2008, particularly since around 2005.

TABLE 1B—PERCENTILES OF ACUTE HOSPITAL LENGTH OF STAY (DAYS)

[2001–2008]

Year	5th	10th	20th	30th	40th	50th	60th	70th	80th	90th	99th
2001	2	2	3	4	5	6	7	8	10	14	32
2002	2	2	3	4	5	5	6	8	10	14	31
2003	2	2	3	4	4	5	6	8	10	13	30
2004	2	2	3	4	4	5	6	7	9	13	29
2005	2	2	3	3	4	5	6	7	9	12	28
2006	1	2	3	3	4	5	6	7	9	12	28
2007	1	2	3	3	4	5	6	7	9	12	27
2008	1	2	3	3	4	5	6	7	8	12	25

Note: Based on a 10 percent random beneficiary sample of FFS HH users; excludes LUPA episodes and includes only episodes where acute hospital discharge occurred within 14 days of the from-date of the 60-day episode claim and the patient's first destination post-discharge under Part A was HH care.

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

Comment: A commenter stated the data and analysis we used to measure real case-mix change do not recognize that technology improvements in recent years enable patients with more complex conditions to be cared for at home.

Response: We appreciate this comment but possess limited information to evaluate it. The data we do have, from OASIS, suggest that episodes for patients using technological treatments at home are not increasing. OASIS data show that the proportion of episodes involving enteral nutrition has declined from 2.9 percent to 1.6 percent between 2001 and 2008; the proportion of episodes involving intravenous therapy or infusion therapy has stayed stable at around 2.2 percent; and the proportion of episodes involving parenteral nutrition remains at 0.2 percent or less during that period. The proportion of episodes with none of those treatments has increased from 94.8 percent to 96.2 percent. These data are inconsistent with the commenter's assertion, but we solicit commenters to provide us in the future with other types of reliable data on this aspect of patient case-mix.

Comment: Many commenters cited improvements in the accuracy of OASIS coding which could more precisely measure patient severity as a reason why we should drop its proposal to address nominal case-mix growth by reducing payments.

Response: Comments referencing coding improvements, such as increasing accuracy, do not recognize that such improvements are an inappropriate basis for payment. Measurable changes in patient severity and patient need are an appropriate basis for changes in payment. Our analysis continues to find only small changes in patient severity and need.

Comment: Commenters stated that the increase in case-mix is due to the HHA's diligence in ensuring proper coding; CMS's implementation of payment reductions would therefore penalize HHAs for proper coding, while the agencies who were not ethical or diligent in their coding would not be affected as much. Furthermore, a commenter suggested that part of the

"nominal" case-mix changes were due to HHAs' past failures to code properly. The commenter stated that when the HH PPS system was first implemented in 2000, HHAs undercoded in a manner that generated insufficient resources to adequately care for the patient. After modifications were made to the HH PPS system in 2008, coding was still not adequate for the patient. The commenter stated that, for these reasons, the baseline average case-mix is much lower than the actual value.

Response: We agree with the commenter's explanation of previous undercoding as a cause of nominal case-mix growth. Over the years, we have issued and revised instructions for OASIS to reinforce the importance of complete and accurate coding. As we have stated in previous regulations, however, Medicare should not inappropriately make greater reimbursements for a patient population whose level of severity has changed relatively little over the years, notwithstanding more-comprehensive documentation of the health status of these patients.

Comment: A commenter stated that much of the increase in case-mix weights is due to HHAs complying with Medicare instructions regarding patient coding consistent with the 2008 version of the HH PPS.

Response: This comment is difficult to address because the commenter does not cite specifically which documents constitute CMS-issued Medicare instructions "consistent with the 2008 version of the HH PPS." Nor does the comment explain how the increase in case-mix weights was driven by such CMS instructions. However, we believe our release in late 2008 of a revision of Attachment D of the OASIS Instruction Manual would not have had the effect suggested by the comment. (Attachment D was intended to provide guidance on diagnosis reporting and coding in the context of the HH PPS.) First, Attachment D reiterated traditional CMS guidance about how to select diagnoses in home health. Attachment D did not deviate from the fundamental and longstanding instruction that reported diagnoses must be relevant to the treatment plan and the progress or outcome of care. Second, Attachment D's release late in the year suggests it would not have had much impact on the 2008 data.

Comment: We received a number of comments stating that HH patients now have more complex conditions than previous populations of HH patients and that such patients previously would have been referred to health care facilities, but are now being cared for at home. Moreover, the commenters stated that other healthcare settings have developed stricter admission requirements, thereby increasing the number of HHA patients with high severity levels. One commenter cited as evidence diversion of patients to home care from inpatient rehabilitation facilities due to the CMS 60 percent rule and skilled nursing facilities' (SNFs') technology increases. The commenters point to such changes as evidence that policy incentives favor the home setting over institutional care, and therefore, case-mix increases are warranted.

Response: We appreciate the comment, but we have little information with which to evaluate the claim regarding diversion to the home care setting. Possibly relevant is that the proportion of initial non-LUPA episodes preceded by acute care within the previous 60 days has declined between 2001 and 2008, from 70.0 percent to 62.7 percent. This indicates more patients are being admitted from non-institutional settings, for example, the community. However, our data do not indicate whether the patients coming into home care without recent care in a Part A setting were diverted from entering such settings in favor of home-based care. Post-acute institutional utilization data perhaps consistent with the comment suggest a decline in inpatient rehabilitation facilities (IRFs) as a source of HH patients, but this decline may have been partly offset by an increase in SNF utilization as a source. For example, the proportion of initial episodes preceded by an IRF stay that ended sometime during the 30 days before HH admission suddenly declined by more than a percentage point in 2005 and declined another 1.5 percentage points by 2008, while the percentage preceded by a SNF stay increased half a percentage point in 2005 and increased another 0.4 percentage points by 2008 (data based on a 10 percent beneficiary sample of initial, non-LUPA episodes). Furthermore, the fact that acute stays, which normally precede stays in institutional PAC settings, are decreasing in the stay histories of HH patients is inconsistent with the idea that the reduction in IRF stay histories is a sign that more patients are coming to HH as a result of diversion from IRF care.

Comment: Commenters stated that the implementation of the payment reductions should be delayed until the validity of data and methods used to calculate the payment reduction can be verified.

Response: The real case-mix prediction model and its application account for changes in the HH patient population by quantifying the relationship between patient demographic and clinical characteristics and case-mix. The relationships in conjunction with updated measures of patient characteristics are used to quantify real case-mix change. The characteristics in the model include proxy measures for severity, including a variety of measures, namely, demographic variables, hospital expenditures, expenditures on other Part A services, Part A utilization measures, living situation, type of hospital stay, severity of illness during the stay, and risk of mortality during the stay. Measurable changes in patient severity and patient need, factors mentioned by commenters, are an appropriate basis for changes in payment. Our model of real case-mix change has attempted to capture such increases.

We recognize that models are potentially limited in their ability to pick up more subtle changes in a patient population such as those alluded to by various commenters. Yet in previous regulations, we presented additional types of data suggestive of only minor change in the population admitted to HH, and very large changes in case-mix indices over a short period. We included among these pieces of evidence information about the declining proportion of HH episodes associated with a recent acute stay for hip fracture, congestive heart failure, stroke, and hip replacement, which are four situations often associated with high severity and high resource intensity. We found declining shares for these types of episodes as of 2005 (72 FR 49762, 49833 [August 2007]). We presented information showing that resource use did not increase along with billed case-mix (72 FR 49833); stable resource use data suggest that patients were not more in need of services over time, notwithstanding the rising billed case-mix weights that suggested they would be. We also analyzed changes in OASIS item guidance that clarified definitions and could have led to progress in coding practice (72 FR 25356, 25359 [May 2007]). We reported rates of OASIS conditions for the year before the beginning of the HH PPS and 2003, and found some scattered small changes indicative of worsening severity but no dramatic changes commensurate with the increase in case-mix weights (72 FR 25359). In our discussion, we cited specific instances where agencies' changing understanding of coding could have contributed to the adverse changes. However, as previously stated, Medicare payments should be based on patient

level of severity, and not on coding practices.

In the July 2010 proposed rule, we identified a very large, sudden 1 year change (+0.0533) in the average case-mix weight by comparing a 2007 sample that we assigned to case-mix groups using the new 153-group system and a 2008 sample grouped under the same system. It is unlikely that the patient population suddenly worsened in severity to cause an increase of 0.0533 in the average case-mix weight in a single year. Furthermore, we concluded that the large change was not due to our use of the new, 153-group case-mix algorithm in 2008, because when we applied the previous case-mix system and the new system to a sample of 2007 claims, the average weight differed very little (the difference was 0.0054). That is, the algorithms in the previous and new case-mix systems provided highly similar case-mix weights on the sample of 2007 claims. We further examined the diagnosis coding on OASIS assessments linked to the 20 percent claims sample and found a large increase between 2007 and 2008 in the reporting of secondary diagnosis codes (see 75 FR 43242 [July 23, 2010]). The use of secondary diagnosis codes in the case-mix algorithm was introduced in 2008 as part of the new case-mix system.

We are not delaying the CY 2011 payment reduction because we consider these various analyses to be strong evidence that agencies changed coding practice markedly when faced with the new case-mix system in October 2000 and when faced with the refined one in January 2008. The conclusions we reached from the available evidence were that a small amount of real case-mix change has occurred; our model measures this amount to be 10.07 percent of the total change in the average weight since the 12-month period ending September 30, 2000. The remainder of the total change resulted from sources of nominal case-mix change as discussed elsewhere in this preamble. These sources include improvements in coding, changes in therapy prescriptions in response to payment incentives, and changes in such elements of the system as OASIS item definitions and coding guidelines. However, as stated elsewhere in this preamble, we are not finalizing the proposed reduction for CY 2012 pending further study relating to the measurement of real and nominal case-mix change.

Comment: Commenters stated that we should change our methodology so that coding and documentation, and not therapy utilization, are the only factors used in calculating "nominal" case-mix changes.

Response: We thank the commenters for their suggestion. However, the model we use is intended to analyze changes in real case-mix over time and does not distinguish whether these changes are due to increases in therapy use or other factors mentioned by the commenter. We do not believe that it would be appropriate to include utilization-related variables such as the number of therapy visits as variables in the model predicting real case-mix change. In addition, the goal of this analysis was to examine changes in measures of patient acuity that are not affected by any changes in provider coding practices.

Comment: Commenters stated that we should eliminate the proposed payment reductions and rather "conduct targeted claims review and deny payment for claims where the case-mix weight is not supported by the plan of care."

Response: While we appreciate the commenters' suggestion, we cannot act on it, because our resources are not sufficient to conduct claims review on a scale that would be required to counteract the broad-based uptrend in case-mix weights.

Comment: Other commenters stated that CMS decrease the magnitude of the proposed payment reductions.

Response: We have amended the proposal that would have implemented two successive years of payment reductions, with each year's reduction at 3.79 percent. Instead we are finalizing in this rule only the first year's reduction (for CY 2011) while we study additional case-mix data, and methods to incorporate such data, into our methodology for measuring real vs. nominal case-mix change. In the CY 2012 proposed rule, we will make proposals concerning any payment reduction for CY 2012 based on results of those studies and based on claims samples updated through CY 2009. In previous rules, we have stated our intention to incorporate additional types of data, such as Part B data, into our methodology. Efforts so far have been inhibited by problems of data adequacy. In the coming year, we intend to draw on more resources and expertise than we have in the past in order to move forward in completing the examination of additional kinds of data for measuring real vs. nominal case-mix change. As we have stated elsewhere in this regulation, the various types of information and data pointing to the conclusion that nominal case-mix change has been responsible for most of the case-mix growth go beyond the model predicting real case-mix. Much of that extra information cannot be converted into a quantifiable measure, but it is nevertheless very significant in explaining nominal case-mix growth.

Comment: Commenters stated that we should eliminate the case-mix reductions altogether and find other methods to prevent upcoding and "manipulation of therapy and co-morbid condition factors."

Response: We appreciate the commenter's suggestion. As stated elsewhere in this preamble, the payment reductions we proposed were to compensate for past nominal change in case-mix weights that resulted from changed coding practices and/or instructions and behavioral changes among agencies, such as changes in therapy visits prescribed. One approach addressing therapy factors would be to conduct medical necessity evaluations during episodes. An approach to limiting a change in comorbid-condition coding exacerbated by a change in disease definition would be to eliminate hypertension from the case-mix system. We believe these are two proposals that capture the spirit of the commenters' suggestion, but in both instances, we received many comments in opposition. However, we welcome suggestions of other policies that can prevent upcoding and manipulation of case-mix measures.

Comment: Commenters stated that we should suspend or drop case-mix adjustments because adjustment should instead focus on case-mix groups with high weights due to therapy.

Response: The 2008 case-mix model's four-equation structure incorporated a procedure that decelerated payments as therapy visits per episode increase. We plan to recalibrate the case-mix weights in the coming year, and in so doing we will examine our policy of imposing within the case-mix model this deceleration in payment increases. Such examination could lead to an approach suggested by the commenter, were we to more aggressively impose the deceleration. For 2011, we are proposing to maintain the set of case-mix weights we issued in 2008.

Comment: Similarly, commenters stated that we should "target agencies with excessive therapy usage" instead of implementing the proposed payment reductions.

Response: We have not conducted an analysis to identify agencies with excessive therapy usage. We believe that what constitutes excessive therapy must be judged in view of the patient's need during the episode. It is impossible to conduct an analysis that takes the amount of individual need into account based on the information we have; in fact, that is the reason we implemented therapy thresholds in the first place: A

shortage of information on the OASIS sufficient to predict the amount of therapy needed by the patient. What we do have is strong evidence that in general therapy prescriptions changed dramatically under the HH PPS, in response to payment incentives. These prescriptions changed again with the implementation of the revisions to the HH PPS case-mix system in 2008; notably, between 2007 and 2008, we observed a 3-percentage point increase in the percent of episodes with 14 or more therapy visits. Such behavioral change was part of the nominal change causing expenditures that we are now recovering with the case-mix reductions to the rates.

Furthermore, even if agencies with excessive therapy usage were identifiable in an administratively feasible manner, a separate set of concerns relates to the effect on beneficiaries from targeting agencies in the way suggested by the commenters. We are concerned that a policy of targeting agencies with excessive therapy usage might unfairly penalize certain patients. For instance, even in an agency that pads the therapy prescription to reach a certain threshold, there will likely be some patients who need all the therapy visits prescribed. A payment reduction limited to certain agencies is likely to unfairly penalize some of the agency's patients. In addition, as previously stated, we believe that nominal case-mix change has been widespread and that therefore overpayments were widespread as well.

Comment: Commenters stated that we should suspend or drop case-mix reductions in favor of the approach in S.2181/H.R. 3865 (110th Congress), which involved working with the HH industry to develop criteria and evaluating a medical records sample to determine reductions, rather than relying on hypothetical extrapolations. Another commenter mentioned that the Home Health Care Access Protection Act (S. 3315/H.R. 5803) was introduced to "establish a more reliable and transparent process for CMS to follow in evaluating Medicare payments for home health services." The commenter asked if CMS would be willing to cosponsor this legislation.

Response: We intend to work with representatives of the HH industry as we pursue a review over the coming year of the data and methods for measuring real case-mix change. Theoretically, a medical records sample might work, but as a practical matter, we strongly suspect it might not work. It is unlikely that we could finance the collection of samples large enough to produce reliable results. It is expensive to abstract medical records, and we would need a sizable sample of records from the IPS period and from a follow-up year (for example, 2009). Based on our experience in a context involving the retrieval of years-old records, it is not likely that we could find enough records to constitute a valid broad-based sample. The procedure would have nurses group them into a case-mix group, and compare the results with those from a similar procedure performed on recent records. Additional potential problems with using medical records include the strong possibility that records would have insufficient information to allow assignments for the Activities of Daily Living (ADL) items of the case-mix system, have insufficient information to enable independent staging of pressure ulcers, and other kinds of underreporting. It is possible that this procedure might *not* return the findings that the proponents suggest it would, because the nominal case-mix change problem partly results from reporting practices that have changed through time from a state of underreporting to a state of more complete reporting. Therefore, one would expect that the source records would likely reflect underreporting in the early years, just as the OASIS reflected underreporting in the early years.

Comment: One commenter stated that detailed information about the method to calculate the baseline values was not released to the public. Commenters questioned the validity of the 2000 data used to calculate the baseline. Commenters stated that in 2000, there was a limited amount of OASIS data and the data submitted might not have been completely correct. One commenter expanded upon this concept by stating that "a consistent, largely reliable database of information from submissions of the OASIS form was most likely not achieved until sometime during 2003". Commenters stated that initially extensive education and training was needed in order to ensure reliable OASIS data. In addition, commenters stated that since Abt Associates was only able to use 313,447 episodes to calculate the base, there were not enough data to ensure that the base was correct, and therefore, "the final period of IPS should not have been used as a "base" to measure anything."

Response: In our May 2007 proposed rule and our August 2007 final rule, we described the IPS samples and PPS samples that were used to calculate case-mix change. We remind the commenter that 313,447 observations is an extremely large sample by statistical standards, and that agencies began collecting OASIS data in 1999, following issuance of a series of regulations beginning on January 25, 1999 (64 FR 3764). Most of the data we used for the baseline period come from the first 3 quarters of the year 2000—months after collection was mandated to begin in August 1999. By 2000, the vast majority of agencies were complying with the reporting requirements. We question the idea that agencies took three more years to come up to speed with OASIS. We believe the commenter overstates the amount of training needed to complete OASIS reliably. The licensed personnel responsible for assessing patients do not and should not need all the extensive training implied by the comment, because assessment is part of the foundation of their training and professional skill. Indirect evidence that the data from the early years of the HH PPS were sufficiently reliable comes from model validation analysis we conducted during that period. Validation of the 80-group model on a large 19-month claims sample ending June 2002 (N = 469,010 claims linked to OASIS) showed that the goodness-of-fit of the model was comparable to the fit statistic from the original Abt Associates case-mix sample (0.33 vs. 0.34), notwithstanding that average total resources per episode declined by 20 percent. That analysis also showed that all but three variables in the scoring system remained statistically significant.

Comment: Commenters noted that OASIS data from Outcome Concepts Systems demonstrated increased patient acuity from 2006–2008 as measured by ADL and Instrumental Activities of Daily Living (IADL) assessments of decreasing functional capabilities of HH patients. OASIS data demonstrated a "large increase" in acuity as measured by changes in clinical conditions, the number of patients requiring IV therapy, parenteral nutrition, those that have urinary tract infections at the start of care and those with increased inability to manage oral and injectable medications; these commenters noted that OASIS measures were not likely to be "upcoded" to secure higher reimbursement as none had a direct or indirect impact on the level of payment under HH PPS. Further, the decrease in functional capabilities could have been easily correlated with increase in the use of therapy services as both physical and occupational therapists directly address the ADL incapacities that are the focus of these OASIS findings. The commenter referred to reports on the July 23, 2010, Proposed Rule

commissioned by the Home Health Advocacy Coalition and the National Association for Home Health and Hospice, saying both documents indicate "non-case-mix related OASIS items, such as grooming and light meal preparation have shown increasing functional limitations among home health patients."

Response: We believe the commenter is in error in stating that intravenous therapy and parenteral nutrition are not used in the case-mix system. Another inaccuracy in this comment pertains to the cited changes in the frequency of these technological treatments at home, which in fact are not increasing. A large, random sample of OASIS data linked to claims shows that the proportion of episodes involving intravenous therapy or infusion therapy has remained stable at around 2.2 percent and the proportion of episodes involving parenteral nutrition remains at 0.2 percent or less during that period. We are reluctant to use OASIS data to analyze changes in real case-mix because OASIS measures reflect changes in coding practices and payment incentives including quality measurement incentives, all of which are not related to real changes in patients' acuity. We are also concerned that incentives could lead to reports of patient function—whether or not particular function-related items are used in the case-mix assignment—that are consistent with the therapy visits planned. Unfortunately, this problem potentially limits the usefulness of non-case-mix items. We believe that independent measures are the best way to ensure the reliability of our real case-mix methodology. We plan to try to identify independent measures, beyond the independent measures we are currently using in our methodology, as we go forward.

Comment: A commenter stated the case-mix change analysis is flawed in that it relies on hospital DRG data, whereas more than half of Medicare HH patients are admitted to care from a setting other than a hospital, and if they were in a hospital, the HH admission followed much later.

Response: We disagree that the utility of the hospital information in the case-mix change analysis is so limited. Regardless of whether the patient came directly from a non-hospital-setting (for example, home or a post-acute institutional stay), information from a hospital stay preceding HH is typically relevant to the type of patient being seen by the HHA, and thus can provide information about the PPS case-mix measure for the HH episode. A recent hospitalization, whether or not there is an intervening period spent in some other setting before HH admission, is common before admission to home health. Data from a 10 percent random beneficiary sample of HH users indicate that a hospitalization history for new admissions is far more common than the comment may suggest. In 2008, 45.3 percent of patients admitted to home care for a non-LUPA episode had an acute stay within the previous 14 days; 56.1 percent had an acute stay within the previous 30 days; 60.3 percent had an acute stay within the previous 45 days; and 62.7 percent had an acute stay within the previous 60 days. We could have restricted the real case-mix change analysis to new admissions to home health, but because we received many questions about the completeness of the information to be obtained from such an approach, we decided to use all 60-day episodes in the analysis. We believe using all 60-day episodes in the analysis is reasonable, since a majority of new admissions to HH complete their stay in HH within a 60-day episode. Furthermore, non-initial episodes, though they are less than half of episodes in our analysis, are not devoid of recent hospital information. When we look at all new HH admissions, we find that about 15 percent are hospitalized within 30 days of admission (that is, within the first 30 days of the first episode), with the risk of hospitalization rising beyond the 30th day. Many of these hospitalized patients return to HH after discharge, making data for returnees available for our analysis of the acute stay history. While we do not have information specifically about the hospitalization risk of the new admissions who go on to recertification episodes, it seems reasonable to infer that they have risks similar to the overall average 30 day hospitalization rate of 15 percent. The Abt Associates case-mix change report ("Analysis of 2000–2008 Case-mix Change," July 2010, link at *http://www.cms.gov/center/hha.asp*) indicates that about 90 percent of the episodes have a hospitalization history in the data (p. 6), looking back a maximum of 4 years. However, from the information we show here about the likelihood of a hospital stay before and after home health, relatively few of the hospital stays contributing information are as old as 4 years. We also note that the remaining 10 percent of episodes are not dropped from the analysis; these episodes contribute information for the model, specifically, demographic information and various proxy measures derived from Part A utilization and expenditure data.

Comment: Commenters suggested that CMS should also recognize that HH patients are often treated for conditions other than the primary reason for their hospitalization. Furthermore, commenters stated that the primary reason for HH care may be different from the primary reason why a person was admitted into the hospital. Therefore, commenters stated that the DRGs used in the real case-mix prediction model may not be relevant to the patient's condition in the HH setting.

Response: We thank the commenters for their input. However, we would like to remind commenters that the real case-mix prediction model is not limited to diagnoses from inpatient claims. The model also takes into account demographic factors, as well as utilization indicators of health status. Moreover, the model measures the relationship between these factors and case-mix.

Comment: Some commenters stated that payment rate reductions due to case-mix weight changes are not warranted because Medicare expenditures on HH are well within budgeted levels, thereby demonstrating that aggregate spending has not increased enough to permit CMS to exercise its authority to adjust payment rates. Commenters cited budget projections of the Congressional Budget Office (CBO). Another commenter stated while therapy services for HH patients have increased in volume since the start of the HH PPS in 2000, patient outcomes have improved and Medicare spending per patient and in the aggregate overall has stayed well below projections by the CBO. Some commenters stated that payment reductions in HH will lead to more institutional care, for example, by leading to increases in hospital readmissions of post-acute patients.

Response: A CBO projection table shown in one of these comments indicated that, based on projections of March 2004, spending has exceeded projections in 3 of the 5 succeeding years. We have no statutory authority to consider the relationship of CBO projections to HH outlays when setting the HH PPS payment rates. The Secretary's authority to respond to nominal coding change is set out at section 1895(b)(3)(B)(iv) of the Act. There is no evidence that improvement in HH patient outcomes is related to the level of payments achieved through nominal case-mix change. Effects of payment reductions on access and patient outcomes are worthy of study, using carefully designed research. We are aware of the challenges of

conducting conclusive research in this area, in part because other policy changes affecting the study question may co-occur. We have noted elsewhere in this preamble that we intend to request that the Office of the Inspector General resume investigations of the access impacts of payment reductions.

Comment: A commenter stated that a typical case-mix weight change adjustment in other sectors may bring a reduction in profit margins only, whereas in home health the adjustment occurs where the higher payments from increased case-mix weights are offset by increased costs.

Response: Analysis of profit margins indicates that they remain high among HHAs. For example, Medicare margins were 17.4 percent in 2008. This situation suggests that higher payments are not necessarily being offset by increased costs. In March 2010, MedPac estimated that Medicare margins will be 13.7 percent in 2011, taking into account the then-expected payment reduction of 2.71 percent to account for nominal case-mix change (MedPac, *Report to the Congress: Medicare Payment Policy,* March 2010). Our estimates suggest aggregate Medicare profit margins in HH will remain in double digits in 2011 under the payment policies proposed in the July 23, 2010, proposed rule.

Comment: Commenters stated that therapy utilization is a coding adjustment that accompanies not only an increase in reimbursement but also an increase in provider costs, implying that a rate reduction related to increased costs is inappropriate.

Response: We believe that the goal of the Medicare program is to ensure that beneficiaries receive the right care at the right time. The evolution of patterns of therapy utilization since the PPS began leaves doubt that appropriate care has been provided. In the CY 2008 proposed regulation (72 FR 25356) we described a shift in the distribution of therapy visits per episode under the HH PPS that caused two peaks: One below the therapy threshold of 10 therapy visits and the other in the 10 to 13-visit range. Before the HH PPS, the distribution had one peak, at 5 to 7 therapy visits, well below the 10-visit therapy threshold in use prior to the 2008 refinements to the HH PPS. Table 2 shows the distribution of episodes (LUPA and non-LUPA) changed again with the implementation of the 153-group case-mix system and its revised set of thresholds and therapy steps. At the new 7-visit step (7 to 9 visits) there was a sudden 50 percent increase in the proportion of episodes, and at the new 14-visit therapy threshold, there was a 25 percent increase in the proportion of episodes. One commenter, in writing about the questionable prescription of therapy treatment, stated that certain agencies have habitually provided therapy to patients whose natural course of recuperation would have been the same regardless of receipt of therapy. We also note that we implemented a declining payment with each added therapy visit with the 2008 refined case-mix system, with the intent to deter inappropriate padding of therapy prescriptions to higher and higher numbers of visits, as we added new thresholds above 10 visits. However, the pliability of therapy prescriptions, the continued growth in the proportion of episodes utilizing therapy, and the 25 percent increase in the proportion of episodes with high numbers of therapy visits (14 or more) may be evidence that increased costs are more than offset by the increased payment associated with therapy. Therefore, it is not certain that a rate reduction related to increased costs is inappropriate.

TABLE 2—DISTRIBUTION OF HOME HEALTH EPISODES ACCORDING TO NUMBER OF THERAPY VISITS

[2002–2008]

Number of therapy visits	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)
None	54	52	51	50	50	50	50	49
1 to 5	14	15	15	15	15	15	14	14
6	3	3	3	3	3	3	3	3
7 to 9	6	6	6	6	6	6	6	9
10 to 13	10	11	13	14	14	15	15	10
14+	12	12	12	12	12	12	12	15

Comment: A commenter stated that the increase in case-mix due to increased therapy services should count towards the "real" case-mix changes, not towards the "nominal" case-mix changes. The commenter thought that as long as the agency provides therapy, the changes in case-mix due to increased therapy services should be considered "real."

Response: We based our nominal change estimate on beneficiary characteristics information, which when applied to the prediction model for real case-mix, to account for whatever changes in patient severity that have occurred since the IPS baseline. The remainder of the change in the national average case-mix weight is classified as nominal. We have not netted out from our estimate of nominal case-mix change any increases in the weights due to additional therapy utilization, because utilization is an aspect of the case-mix system that is under the control of providers, and therefore, is not necessarily a reflection of changes in patient severity, especially in view of the fact that our use of the real case-mix change model accounts for changes in patient severity. Furthermore, the evolution of therapy utilization under the HH PPS suggests that some of the therapy provision under the HH PPS has been subject to financially driven decision-making and as such, it is akin to nominal case-mix change, so we have classified it with nominal change.

Comment: A commenter stated the real case-mix change analysis omits consideration of increased therapy needs in the population. Other commenters stated that therapy use changes were not explained in the model and that CMS admitted that it could not explain the correct amount of therapy expected for patients. The commenter stated CMS should use alternative variables that would be more indicative of the changes in therapy use.

Response: The models were intended to analyze changes in case-mix over time and do not distinguish whether these changes are due to increases in therapy use or other factors. We do not believe that it would be appropriate to include utilization-related variables, such as the number of therapy visits, as predictors in the model, as such, variables are provider-determined. In addition, the goal of these analyses was not to develop refinements to the payment system but rather to examine changes in measures of patient acuity that are not affected by any changes in provider coding practices. CMS has

access to the claims histories and other administrative data for patients in our samples, and we welcome suggestions about how to better use these resources in finding alternative variables more indicative of the need for therapy. Such proposals must recognize that the desirability of any proposed alternative data depends on whether the data generation process involves HH providers.

Comment: A commenter stated that fewer therapy services are being provided in other care settings and therefore, the increases in therapy usage are due to patients' increased need for therapy services in the HH setting.

Response: We have no information suggesting that fewer therapy services are being provided in other care settings. In the SNF setting, more therapy is being provided to SNF patients than used to be the case. This is indicated by the increased share of SNF days for therapy RUG–III groups; the share grew from 75 percent to 85 percent between 2000 and 2006. MedPac has documented increases in rehabilitation intensity in SNFs since 2002 (MedPac, *Report to the Congress, Medicare Payment Policy,* March 2010). For patients who go on to HH from Part A institutional settings, we have no evidence of less therapy utilization in prior settings. We have evidence to the contrary. For example, total billed charges for therapy from all previous Part A settings within the 14 days before HH admission nearly tripled, from an average of $1,154 (2001) per person with any Part A discharge to $2,952 (2008). Total billed charges for therapy increased from $2,068 in 2001 to $3,680 in 2008 per person with any prior Part A stay involving therapy.

Comment: A commenter suggested that CMS "analyze case-mix weight changes based on data beginning in 2005" and "analyze case-mix weight changes for 2008 to current to see how much increase occurred in more recent years." Furthermore, the commenter recommended that CMS "use national benchmarking companies for data if CMS does not have data yet available."

Response: We will be turning to analysis of 2009 data later this year. Unfortunately, the time it takes for a complete year of data to arrive and the added time of cleaning, processing, summarizing, and linking the data currently preclude using the data for the analysis in this final rule. We have concerns that data from benchmarking services would not be nationally representative. Therefore, we intend to use random samples drawn from our own administrative data.

Comment: A commenter believes that the model fails to account for any changes in HHA behavior related to patient populations served. These changes would include a marketing effort targeted to increase the proportion of patients who are high users of therapy. The commenter also stated that the post-acute care industry has changed dramatically since the Abt regressions were first designed. The current use of administrative claims data by Abt and CMS is inadequate, and perhaps even counterproductive. This practice sends the wrong signals as to how HH and facility-based care should be related as the Medicare program moves toward an era of "bundled payments" and other initiatives to coordinate care across settings.

Response: We disagree with this comment. The predictive model for real case-mix was designed in 2007 and includes a comprehensive set of variables. The model looks at case-mix change across a large sample of providers, rather than considering individual provider behavior. If the characteristics of patients have changed due to marketing efforts, this should show up as changes in the mean values of patient characteristics over time. For example, the increase in knee replacement patients since the baseline year causes an increase in the predicted case-mix weight. We will continue to research ways to modify our models and data for analyzing real case-mix change over time. A challenge with using OASIS items is that, for the most part, OASIS items associated with case-mix are already used in the grouper and thus are not appropriate to use in the case-mix change analyses (since changes in case-mix over time may be due to coding changes rather than changes in severity).

Comment: Commenters stated that the model is based on administrative data rather than clinical data.

Response: The model only includes a few variables that are derived from OASIS assessments (measures of patient living arrangement) because the OASIS items can be affected by changes in coding practices. It is not practical to consider other types of HH clinical data (for example, from medical charts) in the model.

Comment: A commenter wrote that the model relies too heavily on assumptions and beliefs rather than empirical evidence.

Response: We disagree with the commenter. The prediction model for real case-mix is an empirical model, the findings of which are based entirely on empirical evidence.

Comment: A commenter stated CMS should suspend nominal case-mix-related payment reductions until it develops an accurate and reliable model to evaluate changes in case-mix weights consistent with the whole nature of patients served in HH care, not just those discharged directly from hospitals.

Response: The commenter does not recognize that many variables in our model are applicable to patients who have not used hospitals recently. Variables relating to demographic status and PAC utilization are among the model's variables. Another set of the model's variables, used to describe the nature of any previous hospital stay, applies to many patients nonetheless, because we searched the claims history to find the last hospital stay that occurred before the episode. We believe that the model includes a rich set of patient measures. Efforts will continue to deploy more information in evaluating changes in HH patients' health characteristics. It is important to note that the omission of any particular variable is not enough to change estimates of unpredicted case-mix change. Variables must have different prevalence rates in the initial and later periods. If prevalence rates for such variables were the same in both periods, the effects would net out; in other words, there would be no systematic difference in the predicted case-mix over time.

Comment: One commenter stated that the "2008 additional case-mix ICD–9 codes and therapy four-equation model logically results in increased case-mix and contributes to the faulty foundation of comparison with IPS and early PPS data."

Response: We disagree with the commenter. We performed our research leading to the four-equation model using an extremely large sample of claims linked to OASIS assessments. Using visit times by discipline reported on the sample of claims, we studied the relationship of the total of wage-weighted visit times per 60-day claim to patient characteristics as reported by agencies on the assessments. The wage-weighted minutes are the best measure available of the cost burden of caring for the patient, given his or her clinical characteristics. This method essentially replicated the original method we used to develop the 80-group case-mix system during the period before OASIS was implemented and before per visit line billing was required. A prototype of OASIS was used at that time. The 2005 coding and reporting practices, as well as the resource use patterns, were the foundation of the 2008 refinements,

along with our replication of the basic analytic approach. We know of few other methods comparable in their ability to yield a fair and representative case-mix model for national application. Given the essential continuity in approach, we fail to see how the 2008 refined model specifically is a reason not to make comparisons with pre-PPS and early PPS data. Our comparisons of population and utilization characteristics, which are the basis for our prediction model of real case-mix, do not involve use of the HH PPS case-mix payment variables or the ICD–9 codes reported by agencies.

Comment: Commenters stated that the Abt report on the real case-mix change analysis ("Analysis of 2000–2008 Case-mix Change", July 2010, link at *http://www.cms.gov/center/hha.asp*) does not discuss what signs are consistent with known relationships and, hence, is not in a position to judge the signs of the coefficients. In addition, commenters stated that while Abt included variables related to inpatient stays, the estimated coefficients are not consistent with expectations that "the coefficient for any stay would be positive and the coefficient for the number of days would be negative." The coefficient has an opposite sign than what is expected.

Response: We thank the commenters for their comments. However, our purpose is to predict case-mix weights using all available and relevant administrative data, rather than to isolate the impact of individual variables. We have noted elsewhere that many coefficients have signs as we expect (Abt Associates 2008; CMS 1541–FC, FR August 29, 2007). Contrary to what the commenter states, it is not clear that a hospitalization would be associated with higher case-mix; it may be that community patients are more clinically complex and have a higher case-mix than those who are discharged from a hospital to home health. This result is consistent with the impact of pre-admission location variables (from OASIS item M0175) in the 80-group case-mix model.

Comment: Abt does not perform any multicollinearity diagnostic statistics or consider the remedy of combining some of the variables. The model uses a large number of variables that do not have much variation. The close interaction among the variables "is likely to pose problems with the prediction of the dependent variables."

Response: Given the objectives of the analysis, we are not particularly concerned about redundancy among variables. It is also important to note that such redundancy, often called multicollinearity, does not actually bias results and may only cause large standard errors of the coefficients for variables that are related to one another. Standard errors are not used in our case-mix change calculations. The Abt Associates report described improvement in the predictive power of the model as each set of variables (for example, APR–DRG variables) was added beyond demographic variables alone. The addition of Part A expenditure variables, the last variable set added to the model, led to little improvement in predictive power, and for that reason might be considered redundant; however, their addition did not change the essential results of the analysis (Abt Associates, 2008), which were that only a small proportion of the case-mix growth could be attributed to changes in patients' characteristics.

Comment: Commenters stated that the Abt models are unreliable because 40 percent of the top variables differ from one model year to the next (original IPS model and the model rebased to 2008 data), and 20 percent of the variables change signs. Commenters also stated that the model CMS uses to assess case-mix weight changes should be at least as accurate and reliable as the case-mix adjustment model that it is assessing. The current PPS case-mix model reportedly originally had an R-squared explanatory power of over 40 percent while the case-mix weight change assessment model falls far short of that benchmark. Commenters stated that the explanatory power of the models falls 46 percent from the original model to the rebased model. The regression model R-square dropped from 19 percent to 10 percent in the 2008 analysis. The R-square of the 80-group HHRG model was at 0.21—much lower than the R-square for the 153-group HHRG model at 0.44. The commenter stated this high R-square of the current PPS case-mix model suggests that the case-mix weight change regression model analysis for 2008 should have had a higher R-square. The decrease in the R-square is "unclear and unexplored."

Response: We thank commenters for their comments. However, we disagree that the difference in R-squares for the two models indicates that the prediction model for real case-mix is unreliable. The nine top drivers of case-mix are the same in both models, as are 15 of the top 20. Most of the predicted case-mix change results from the major "drivers" in the model, and, of the top 50 drivers of case-mix change (which account for more than 60 percent of the total predicted change in the model), 37 have the same sign in both models and the correlation between the coefficients from the two regression models is 0.56. Of the variables that changed signs, most were not statistically significant. We would expect some change over time in the variables that are among the top drivers of case-mix change, given the large number of variables in the model and the differing dependent variables (the 80 case-mix weights for the first model and the 153 case-mix weights for the second model). With regards to the 40 percent R-squared explanatory power benchmark, given that the goal of the case-mix change analyses is to determine the extent to which case-mix changes observed over time are due to changes in patient acuity or other factors (such as coding changes) that are not observed in the model, we do not believe that this is an appropriate statistical performance benchmark for the model.

The explanatory power of the current HH PPS case-mix model is as high as it is in large part because of the therapy-related variables in the model (where a direct measure of resource use is included on the right-hand side of the regression model). We do not believe that it is appropriate to include these types of variables in the case-mix change model because they are provider determined.

Comparing the statistical performance of the two prediction models for real case-mix is not really appropriate to compare strictly the statistical performance of the two models, given that we had to drop the living arrangement variable from the second model and that the dependent variable for each model is a different set of case-mix weights. We also note that a possible contributor to the lower R-square for the second model is the large amount of nominal case-mix change that occurred between 2000 and 2008. Changes in coding practice and resulting assignment of case-mix weights could have led to a situation where the predictor variables in the prediction model for real case-mix collectively have less ability to predict the weights than when the variables were first used with the data from the last year of IPS (2000) to predict the original PPS case-mix weights.

Comment: A commenter stated that no explanation was provided on segmented choice of periods of evaluation. This commenter wrote that it is unclear why Abt subdivided the 2000–08 period into 2000–2007 and 2007–2008. To minimize the possibility for shifts in the relationship between resource requirements and explanatory variables, Abt could have subdivided the 8-year period in half or at least

performed some sensitivity analysis to choose the time periods.

Response: The procedure of identifying nominal case-mix change relies on subtracting an average of predicted weights from the average of actual, billed weights. The case-mix group system changed from one of 80 groups to 153 groups in 2008, causing a change in the set of weights that could be billed to Medicare. Up until 2008, this was not an issue as the same set of weights was used throughout the entire history of the PPS up until that year. To be able to bridge the periods before and after the 153-group model, we rebased the prediction model to the 2008 data, the first year that the 153-group model was used for paying HH providers. We combined the results from the original IPS-period equation with the results from the rebased 2008 equation for this year's analyses. Our application this year of the IPS-period equation was unchanged (except for certain technical changes in the APR–DRG grouper) from our application of it for last year's rule.

Comment: A commenter stated hospital discharge data demonstrate that HH patients are admitted from hospital stays with a higher degree of acuity than in the past. "The acute care (inpatient prospective payment system (IPPS)) CMI for cases discharged to HHAs reflects the patient severity of the patients discharged to home health agencies. As one of the measures for patient severity is prior hospitalization, it is believed to be unaffected by the HH CMI. The CMI for the prior hospitalization can be assumed to be a proxy measure of the "real" case-mix index. Based on our analyses of the 2007 and 2008 MedPAR data (Medicare discharges from short term acute care hospitals), we found that the CMI (MS DRG-based CMI) of cases discharged to HHAs increased by 2.5 percent from 1.588 in 2007 to 1.63 in 2008. Furthermore, we also found that among the acute care cases discharged to HHAs, the proportion of cases categorized as Medicare Severity Adjusted Diagnosis Related Groups (MS DRGs) with complications and comorbidities increased by 3 percentage points from 25 percent in 2007 to 28 percent in 2008. This implies that the real case-mix index due to comorbidities most likely increased for the cases discharged to home health agencies."

Response: The MedPAR data analyzed in this comment cover the period when the MS–DRG system was implemented. We analyzed MS–DRG coding and found evidence of changes in coding and documentation practices that led to increases in billed acute care case-mix weights. CMS actuaries estimated that a 2.5 percent increase in case-mix in the hospital IP PPS was due to coding and documentation changes occurring in FY 2008 (75 FR 50355). The results cited by the commenter may have reflected the weight-increasing hospital coding behaviors addressed by the CMS regulatory analysis. Therefore, we have reason to believe that this measure alone is not good evidence for assessing real case-mix change. We must also point out that our analyses employing the APR–DRG system indicated that the proportion of episodes with a Mortality Risk Level 3 (Major) diagnosis increased over time while the proportion with Mortality Risk Level 2 (Moderate) decreased. However, our regression coefficients (for both the IPS and 2008 model) showed a negative relationship between being in the moderate or major risk of severity groups and case-mix. Thus, the increase in the proportion of patients in the highest mortality risk category led to an estimate of lower predicted case-mix. Given these types of findings, it is not clear the extent to which the CMI changes that the commenter notes, even if they represented an accurate measure, would lead to a prediction of higher case-mix.

Comment: Several commenters suggested we conduct an impact analysis of the proposed rule relative to case-mix, include an evaluation of access in each year of any adjustment, and consider all factors related to access. These commenters felt that the impacts in the proposed rule were factually and legally inadequate, and therefore, violated the Regulatory Flexibility Act (RFA). A commenter stated we should include an evaluation of the effect of the proposed rule on Medicare spending "in a whole sense," not just the effect on HH services spending.

Response: We have provided a complete and comprehensive analysis for the upcoming calendar year. As in past years, we will address options for regulatory relief for the succeeding calendar year in the year before the rate update becomes effective. There is no language in the RFA that requires an analysis of "out-year" expenditures. The state of the art is not adequate for forecasting effects on all Medicare spending.

Comment: Commenters suggested that CMS remove the case-mix adjustment for medical supplies unless CMS can develop a method to accurately determine what percentage of the case-mix change is "real" and what percentage is "nominal."

Response: We believe that coding practice changes have affected the case-mix assignment for the nonroutine medical supplies (NRS) payment level. The OASIS items used in making the case-mix assignment are potentially vulnerable to the same types of forces that affect coding for the episode case-mix group, that is, improvements in coding and more complete coding, more specific definitions, increased reporting of secondary diagnoses, and other causes of coding practice change. However, since the nominal case-mix change measure was designed to apply to the episode case-mix system, the nominal case-mix change measure may not directly apply to the NRS case-mix model. Therefore, we will defer the application of the payment reduction to the NRS conversion factor for CY 2011 until a review of the nominal case-mix change measure can be performed.

Comment: Commenters stated that it appears that the CMS case-mix weight change analysis never specifically evaluated any evidentiary basis for its determination that the hypertension diagnostic coding was a nominal change in case-mix. Instead, we assume that the increased coding of hypertension is upcoding.

Response: We proposed to delete ICD–9–CM code 401.9, Unspecified Essential Hypertension, and ICD–9–CM code 401.1, Benign Essential Hypertension, from the HH PPS case-mix model's hypertension group, in order to correlate with the goals of our HH PPS case-mix system.

We continue to be concerned that the increase in reporting of unspecified hypertension and benign hypertension signals that continued inclusion of these codes in our case-mix system threatens to move the HH PPS case-mix model away from a foundation of reliable and meaningful diagnosis codes. As we described in our proposed rule, the data indicate a jump of approximately 12 percentage points in the reporting of unspecified hypertension when the refined HH PPS added hypertension as a case-mix code in 2008. The proposed rule also described that the data suggested no HH added resource requirements are associated with hypertension, unspecified, which is by far the most commonly reported hypertension code.

In our proposed rule, we also described that the classification of blood pressure (BP) was revised in 2003 by the National Heart, Lung and Blood Institute (NHLBI) in their "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (the JNC 7 report) and published in the May 21, 2003, Journal of the American Medical Association. These revisions

provided specific clinical guidelines for prevention, detection, and treatment of high blood pressure. A key aspect of the guidelines includes the introduction of a "pre-hypertension" level for individuals with a systolic blood pressure of 120–139 mm Hg or a diastolic blood pressure of 80–89 mm Hg. This recognition represented a change from traditional medical views on the implications of blood pressures slightly above 120/80. If an individual is designated as pre-hypertensive, the guidelines stipulate that this individual will generally require health promoting lifestyle modifications to prevent cardiovascular disease. We described our concerns surrounding the new guidelines for hypertension which we suspected might have led to an increased prevalence of codes 401.1 and 401.9 in 2008 HH claims, along with some evidence that HH patients with either unspecified or benign hypertension no longer require extra resources. We described that these results appear possibly consistent with a phenomenon in which agencies increased their reporting of hypertension in situations that did not meet the HH diagnosis reporting criteria; the results are suggestive of changed coding practice in which less-severe episodes are being reported with hypertension in 2008 than used to be the case. As such, we described that we believe including codes 401.1 and 409.9 in the HH PPS case-mix model reduces the model's accuracy, and that we do not believe we should be including these diagnoses in our case-mix system. We received many comments opposed to the removal of these codes.

Comment: Commenters stated that currently CMS is penalizing HHAs twice for the nominal case-mix changes due to hypertension coding by proposing to remove the hypertension codes and by including the case-mix changes due to hypertension coding in the calculations for payment reductions.

Response: We disagree with the commenters who believe that, by removing these codes while also reducing HH base episode payment rates due to coding change, we are in effect double-counting for growth in case-mix unrelated to real changes in patient health status twice. We proposed to remove these codes from the case-mix system beginning in CY 2011. Our updated analysis, which measures changes in case-mix, both nominal and real, used data from the inception of HH PPS through 2008. As such, by removing these hypertension codes we would expect a slower growth of hypertension-related nominal case-mix beginning in CY 2011. However, as explained in response to a different comment (below), we are not finalizing our proposal to remove hypertension codes 401.1 and 401.9. We assure commenters that if we were to remove these codes from our case-mix system we would do so in such as way that we would recalibrate our case-mix weights to ensure that the removal of the codes would result in the same projected aggregate expenditures.

Comment: A commenter stated that the 2008 HH PPS methodology is based upon a determination that a hypertension diagnosis indicates a higher degree of resource need and utilization by patients with that diagnosis. Nothing in the CMS analysis indicates that anything other than this original finding is supportable. As such, concluding that an increase in patients with a hypertension diagnosis is anything other than a change in patient characteristics is illogical and in error.

Response: If the underlying proportion of patients with hypertension has not changed, then the increase in the observed prevalence of hypertension is an indication of a change in coding practices, even if it reflects more accurate coding. As such, the increased prevalence is not real case-mix change, as it does not represent cost increases related to the health status of patients.

Comment: Commenters stated that CMS opines that the 2003 changes in diagnostic coding guidance led to the increase in incidence of hypertension coding rather than changes in patient characteristics. However, the 2003 changes were fully operational at the time in 2007 when CMS proposed and finalized the 2008 HH PPS version that includes hypertension as a factor in the patient classification system.

Response: We believe that the 2003 NHLBI guidance ("Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure", *Journal of the American Medical Association,* May 21, 2003) may have led to changes in coding hypertension, but that diffusion of the new information probably occurred over several years. The case-mix model of the Final Rule referenced by the commenter was based on 2005 data.

Comment: One commenter stated that diagnosis codes 401.1 and 401.9 should be retained in the case-mix system, because very often clinically complex patients such as hypertensive heart disease patients will be diagnosed with the code 401.9 while waiting for proper documentation that is required by ICD–9–CM in order to report a more specific diagnosis code. Another commenter urged CMS to perform additional analysis to assess the severity of individuals with hypertension codes 401.1 and 401.9 in order to determine whether these codes should be eliminated. The commenter suggested that CMS look at the resource use and the change in the number of visits for patients with codes 401.1 and 401.9 from 2005 to 2008 and compare them to data on individuals with other hypertensive diagnosis codes, while controlling for differences in patient characteristics.

Response: We find these comments compelling. HHAs are expected to adhere to ICD–9–CM coding guidance. The commenter states that ICD–9–CM coding guidance requires specific documentation be obtained prior to coding certain complex hypertensive diseases such as hypertensive heart disease, and such documentation may take time to obtain. The commenter states that agencies may have no choice other than to code such patients using code 401.9 pending receipt of such documentation. Therefore, for such patients, deletion of these codes may delay access to needed home care. We agree with the commenter who urged CMS to expand our resource use analysis for hypertension codes 401.1 and 401.9 to control for patient characteristic differences, and also compare the resource usage of patients with these codes to the resource usage of patients with other hypertension diagnosis codes. We agree that this suggested comprehensive analysis will enable us to identify whether there are sub-categories of patients currently assigned codes 401.9 or 401.1 who are more resource intensive, such as the hypertensive heart disease patient, enabling us to revise our case-mix system to account only for those resource intensive patients. As such, we are deferring removal of the hypertension codes from our case-mix model pending completion of the suggested analysis.

In the interim, we are committed to slowing the growth of nominal case-mix by addressing the inappropriate reporting of these codes. We plan to target providers for review who have substantive growth in the reporting of these codes, or higher than expected instances of reporting them. We also reiterate the need for providers to follow the OASIS Attachment D coding guidance, found at *http://www.cms.gov/HomeHealthQualityInits/14_HHQIOASISUserManual.asp,* where we explain that providers must only code a diagnosis if it is addressed in the HH plan of care and affects the patient's responsiveness to treatment and rehabilitative prognosis.

Finally, we would like to clarify that page 12 of the 2003 statement by the National Heart, Lung and Blood Institute (NHLBI) "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (the JNC 7 report), published in the May 21, 2003, *Journal of the American Medical Association* explicitly states that prehypertension is not a disease category, which indicates that the coding of 401.1 or 401.9 for pre-hypertensive patients would not be appropriate. This is consistent with pre-existing ICD–9–CM guidance, which describes essential hypertension as SBP of 140 and above.

Comment: A commenter stated that the proposed 3.79 percent adjustment for nominal case-mix change appears to be based primarily on the inclusion of hypertension as a patient diagnosis and modified provision of therapy services consistent with the HH PPS model revision in 2008.

Response: As previously stated, the proposed adjustments for CY 2011 and CY 2012 took into account all of the nominal case-mix growth we measured between the IPS baseline and CY 2008, and netted out nominal case-mix growth that was already accounted for in previous rate reductions. As of last year's rate update regulation, we anticipated a need to compensate for a total nominal growth of 13.56 percent. This year's analysis showed that reductions previously planned to be implemented were not adequate to compensate for the full total of nominal growth (17.45 percent) that has occurred through 2008. Our method for deriving the real and nominal case-mix change percentages did not isolate any specific sources of nominal growth (such as hypertension coding) upon which to base the reduction. However, the proposed rule for CY 2011 described statistics showing a large 1-year increase in hypertension reporting between 2007 and 2008, and it noted that the observed growth in the numbers of episodes with high numbers of therapy visits was unexpected. The proposed rule also discussed evidence beyond hypertension and therapy, such as increased reporting of secondary diagnoses in general.

In summary, in this final rule, we are implementing the proposed 3.79 percent reduction to the national standardized episode rate for CY 2011. We will defer finalizing a payment reduction for CY 2012 until further study of the case-mix change data and/or methodology is completed. In addition, in this rule, we are withdrawing the proposal to apply the case-mix change reduction to the NRS conversion factor. As part of our review of the nominal case-mix change methodology, we will study its applicability to the NRS model. The NRS conversion factor will be updated in CY 2011 by the market basket update of 1.1 percent and will also be adjusted for outlier payments in accordance with section 3131(b) of the Affordable Care Act. We are also withdrawing our proposal to eliminate ICD9–CM diagnosis codes 401.1, Benign Essential Hypertension, and 401.9, Unspecified Essential Hypertension, from the HH PPS case-mix model's hypertension group, pending the results of a more comprehensive analysis of the resource use of patients with these conditions.

B. Therapy Clarifications

In the CY 2011 HH PPS proposed rule, we discussed analyses that suggested that therapy under the Medicare HH benefit, in many cases, was being over-utilized. Analysis of HH utilization under the original single 10-visit therapy threshold suggests that the threshold offered a strong financial incentive to provide therapy visits when a lower amount of therapy was more clinically appropriate. Essentially, the data suggested that financial incentives to provide 10 therapy visits overpowered clinical considerations in therapy prescriptions. For the CY 2008 final rule, we established a system of three thresholds (6, 14, and 20 therapy visits) with graduated steps in between to meet our objectives of retaining the prospective nature of the payment system, reducing the strong incentive resulting from the single 10 therapy threshold, restoring clinical considerations in therapy provision, and paying more accurately for therapy utilization below the 10-visit therapy threshold.

In the proposed rule, we described that analysis of CY 2008 data continues to suggest that some HHAs may be providing unnecessary therapy. MedPAC states in its March 2010 report that 2008 data also reveal a 26 percent increase of episodes with 14 or more therapy visits (MedPAC, *Report to Congress: Medicare Payment Policy,* Section B, Chapter 3, March 2010, p. 203). While this analysis suggested that therapy payment policies are vulnerable to fraud and abuse, the swift, across-the-board therapy utilization changes also suggest another more fundamental concern. MedPAC wrote in the March 2010 report (MedPAC, 2010, p. 206) that payment incentives continue to influence treatment patterns, and that payment policy is such a significant factor in treatment patterns because the criteria for receipt of the HH benefit are ill-defined. MedPAC also reported that better guidelines would facilitate more appropriate use of the benefit.

As such, in the CY 2011 HH PPS proposed rule, we proposed to clarify our policies regarding coverage of therapy services at § 409.44(c) in order to assist HHAs and to curb misuse of the benefit. Specifically, we proposed the following:

- Require that measurable treatment goals be described in the plan of care and that the patient's clinical record would demonstrate that the method used to assess a patient's function would include objective measurement and successive comparison of measurements, thus enabling objective measurement of progress toward goals and/or therapy effectiveness.
- Require 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 least every 30 days during a therapy patient's course of treatment. For those patients needing 13 or 19 therapy visits, we proposed to require that a qualified therapist (instead of an assistant) perform the therapy service required at the 13th or 19th visit, assess the patient, and measure and document effectiveness of the therapy. We would cease coverage of therapy services if progress towards plan of care goals cannot be measured, unless the documentation supports the expectation that progress can be expected in a reasonable and predictable timeframe. An exception to this would be when the criteria for needing maintenance therapy are met.
- Clarify when the establishment and performance of a maintenance program is covered therapy.

Comment: A number of commenters were in strong support of our efforts to rein in abuse and overuse of therapy through sound documentation, objective measurement, and appropriate involvement of qualified therapists. Commenters expressed support for proposed additional requirements of documentation of the patient's clinical record, including therapy treatment goals to be described in the plan of care and objective measurement obtained during the functional assessment. One commenter stated that the elements of documentation added in our proposed regulations are reflective of professional standards for the practice of speech-language pathology. Another commenter expressed general support of our therapy coverage and documentation requirements, including those for patient assessment, physician collaboration, plan of care, goal establishment, evaluation of progress

toward goals through objective measures, and documentation, indicating they are all reflective of professional standards of practice for therapy services, such as those established by named major therapy associations. Another commenter expressed support for the proposed therapy coverage requirements regarding functional assessments, treatment plan revisions, and accurate documentation, indicating that these requirements align with professional standards of clinical practice.

Response: We thank the commenters for their support.

Comment: Numerous commenters expressed concern regarding the provision of the proposed rule requiring that a qualified therapist, instead of an assistant, perform the needed therapy service at the 13th and 19th therapy visits. These commenters stated that therapy visits by a qualified therapist beyond those already conducted on the 1st, 30th, and 60th days would be prohibitively expensive to HHAs and an unnecessary intrusion for patients. A number of commenters suggested that requiring a qualified therapist, instead of an assistant, to perform the needed therapy service every 30 days should be sufficient, stating that requiring a qualified therapist to perform the therapy service on the 13th and 19th visits was excessive. A commenter suggested that because only 15 percent of episodes contained more than 13 therapy visits and only 5 percent of episodes contained more than 19 therapy visits, CMS should consider the increased costs of its proposed required therapy changes versus the actual need for the new requirement. Commenters quoted recent findings of a health care consulting company's survey of HH providers regarding the proposed therapy clarifications, stating that most providers believe the proposed therapy changes would lead to scheduling difficulties for therapy visits and would cause difficulties in employing/contracting qualified therapists. A few commenters asked CMS to delay the implementation date of this provision by one quarter to allow more transition time for providers. Several commenters suggested, as an alternative to the requirement that a qualified therapist perform the needed therapy service at the 13th and 19th visit, that adopting ranges would be more acceptable—for example, allowing the qualified therapist visit to occur between the 11th and 13th visits and again between the 17th and 19th visits. Another commenter proposed that CMS should instead defer to State law requirements, asserting that most States require more frequent qualified therapist supervision of assistants than those in the proposed rule, and the proposal's timeframes would be redundant to State laws. The commenter further stated that the proposed defined timeframes are in conflict with § 409.44(a) as they fail to reflect attention to the patient's individual needs. Further, the commenter suggested that CMS abandon the 13th and 19th qualified therapist visit requirement and instead base the reassessment timeframe on individual care needs and changes in patient status. That same commenter added that assistants utilize their clinical reasoning skills every time they treat a patient and advise the supervising therapist regarding the patient's need for continued skill intervention and grading of treatment and, therefore, the requirement for qualified therapist visits at defined timeframes is not reasonable. A commenter classified all our proposed therapy visit rules as arbitrary at best, as well as calling these latest rules regarding the 13th and 19th assessments capricious. One commenter stated that a requirement to re-evaluate patients at the 13th and 19th visits may not be effective in curbing agencies from inappropriately using the benefit in the long-run, suggesting that some agencies will soon learn how to work the revised system to their benefit. A commenter stated that, while overall therapy utilization has increased, it has led to better outcomes for Medicare beneficiaries and overall spending per Medicare patient has remained well below Congressional Budget Office (CBO) projections. Referring to the aforementioned survey results, the commenter described the surveyed HHAs' concern that the proposed clarifications would result in limited improvements in patient care. Several commenters believed that the proposed changes would have an adverse effect on access to care and timeliness of services provided and that these requirements would result in less direct patient care time. Many commenters stated that the documentation requirements were burdensome and costly. Several commenters feared that these requirements would impede access to care in rural areas where there are shortages of qualified therapists.

Response: We thank the commenters for their suggestions. We continue to believe that to ensure Medicare HH patients receive effective, high-quality therapy services, the frequency that a qualified therapist must assess the effectiveness of services performed by assistants must be more clearly defined in Medicare home health coverage regulations. Longstanding Medicare Conditions of Participation (CoPs) regulations at § 484.32(a) require that HH therapy services be administered by a qualified therapist or a qualified assistant under the therapist's supervision, thus requiring a qualified therapist to supervise therapy services to ensure their effectiveness. We believe that in order to adhere to these regulations, a qualified therapist must periodically perform the patient's needed therapy service during the course of treatment to ensure that the therapy being provided by assistants is effective and/or that the patient is progressing toward treatment goals. These visits ensure that the qualified therapist has first-hand knowledge of the patient in order to identify needed changes to the care plan. Additionally, these visits enable a qualified therapist to determine if treatment goals have been achieved or if therapy has ceased to be effective. We note that some States preclude assistants by scope of practice from making determinations such as whether goals are met. As such, we believe that by requiring a qualified therapist, instead of an assistant, to perform the needed therapy service, assess the patient, and measure and document progress toward goals and/or effectiveness of therapy at defined points in the course of treatment, we would lessen the risk that patients continue to receive therapy after the treatment goals have been reached and/or after therapy is no longer effective.

In response to the commenter who stated that while overall therapy utilization has increased, such increased utilization has led to better outcomes for Medicare beneficiaries, we disagree with the conclusion. In their March 2010 report, MedPAC described that functional measure scores for HH patients continue to improve, but also expressed concerns that the measures may not appropriately depict the quality of therapy provided by HHAs. MedPAC reports that there are no measures, which reflect functional improvement for only those patients that receive therapy services. Instead, the measures reflect functional improvement for all patients. Therefore, we believe that the data do not support the commenter's conclusion that higher volumes of therapy have led to better outcomes. The same commenter, pointing to results of the survey described above, stated that the HHAs believe these proposed therapy coverage clarifications would result in limited improvements in patient care. Again, we disagree with these opinions. We refer the commenter to research studies conducted by Linda

Resnick (of Brown University) et al., entitled "Predictors of Physical Therapy Clinic Performance in the Treatment of Patients with Low Back Pain Syndromes" (2008, funded by a grant from the National Institute of Child Health) and "State Regulation and the Delivery of Physical Therapy Services" (2006, funded in part through a grant from the Agency for Healthcare Research and Quality). Both studies concluded that more therapy time spent with a qualified physical therapist, and less time with a physical therapist assistant, is more efficient and leads to better patient outcomes. In these studies, the lower percentage of time seen by a qualified therapist and the greater percentage of time seen by an assistant or aide, the more likely a patient would have more visits per treatment per episode. The studies also concluded that, although delegation of care to therapy support personnel such as assistants may extend the productivity of the qualified physical therapist, it appears to result in less efficient and effective services. We believe that by requiring regular visits by a qualified therapist during a course of treatment we will achieve more appropriate and efficient provision of therapy services while also achieving better therapy outcomes. Regarding the comment that HH expenditures are below CBO projections, we are unclear on the commenter's suggestion. We believe that the commenter may have been suggesting that the growth in HH expenditures does not warrant our attempts to facilitate more appropriate and effective therapy utilization. If so, we disagree with the commenter. We continue to believe that these improved guidelines, as suggested by MedPAC, are an important step in addressing program vulnerabilities while also improving the quality of services provided. We also disagree with the commenters who believe that a qualified therapist visit every 30 days is sufficient, and that the required 13th and 19th visits are excessive and redundant to many state practice supervision requirements, and that the 13th and 19th visit requirement timeframes fail to reflect the patient's individual needs. As we have noted in this and previous rules, at the inception of the HH PPS we analyzed the amount of therapy a HH rehabilitation patient would typically require during a course of treatment. We used clinical judgment to determine that the typical rehabilitation patient in a HH setting would require about 8 hours of therapy, or 10 therapy visits during a course of treatment. We believe that when the unique condition of an individual patient requires more therapy than a typical Medicare HH rehabilitation patient, such a patient should be more closely monitored by a qualified therapist to ensure that high-quality, effective services are being provided and/or acceptable progress toward goals is being achieved. We also continue to believe that to ensure that this monitoring occurs for all high-therapy needs Medicare patients, we cannot depend on individual state supervision requirements. Instead, Medicare coverage clarifications will ensure that all Medicare HH patients benefit from this oversight. We also disagree with commenters that these policies will lead to an intrusion for patients. To the contrary, research suggests that more qualified therapist involvement would further enhance patient care for those patients needing these levels of therapy. We also note that these policies will not result in additional visits or therapy services provided to the patient. The visit by a qualified therapist would not be in addition to the visit that would otherwise occur, as described in the patient's treatment plan. Instead, the qualified therapist, perhaps instead of an assistant, would perform the therapy service at defined points in the course of treatment. In response to the commenter who questioned whether a comprehensive assessment of the patient would need to occur during these qualified therapist visits, we refer the commenter to the regulation text changes at § 409.44(c)(1)(iv) which describes that the qualified therapist must assess a patient's function using objective measurement of function. In other words, the assessment of function would not be a comprehensive assessment of the patient's clinical condition.

In response to the commenters who expressed cost and access to care concerns associated with these policies we note that current CoPs at § 484.12 already require that the HHA and its staff comply with accepted professional standards and principles that apply to professionals furnishing services by a HHA. Those accepted professional standards include complete and effective documentation, such as that which we described in our proposal. (Section 484.55 of the CoPs already requires that HHAs provide a comprehensive assessment that "accurately reflects the patient's current health status and includes information that may be used to demonstrate progress toward achievement of desired outcomes.") In addition, § 484.2 requires that a clinical note be a notation of contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition, which becomes part of the medical record. Further, § 484.48, our longstanding regulation for CoPs and clinical records, requires that a clinical record containing pertinent past and current findings in accordance with accepted professional standards be maintained for every patient receiving HH services. In addition to the plan of care, the record must include treatment plans and activity orders, signed, and dated clinical and progress notes, and copies of summary reports sent to the attending physician. Because these proposed clarifications to our therapy coverage requirements are consistent with long-standing CoP requirements and accepted professional standards of clinical practice, we would expect that many providers have already adopted these practices.

Also, because CoPs at § 484.32 allow therapy services offered by the HHA to be provided by a qualified therapist or a qualified assistant under the supervision of qualified therapist and in accordance with the plan of care, it is our expectation that HHAs are already utilizing qualified therapists regularly to perform the needed therapy services in order to perform the required supervision of assistants.

We agree with the commenter that most HH therapy patients do not receive 13 and/or 19 visits in their course of treatment. In response to the comments which stated the relatively small numbers do not warrant the 13 and 19 qualified therapist visit and documentation requirements, suggesting instead that we target providers with suspect therapy practices for review, we reiterate that we believe these requirements benefit all patients. We believe that these requirements may also deter inappropriate provision of high levels of therapy, and therefore lessen the risk of the associated inappropriate higher HH PPS payments. In summary, by requiring qualified therapist visits when the amount of therapy reaches those high levels, which also correspond to high payment levels, we believe we can simultaneously achieve better patient outcomes, more efficient provision of therapy, and more accurate reimbursement.

We find compelling the commenters' concerns regarding scheduling difficulties. We believe the commenters' concerns regarding scheduling warrant more flexibility in the timing of the 13th and 19th visit requirements. Therefore,

we have decided to allow for some flexibility associated with the 13th and 19th therapy visit rule for patients. Specifically, for beneficiaries in rural areas, the qualified therapist may perform the needed therapy service, reassessment and measurement at any time after the 10th therapy visit but no later than the 13th therapy visit, and after the 16th therapy visit but no later than the 19th therapy visit. And, if extenuating circumstances outside the control of the therapist preclude the therapy service visit, reassessment and measurement at the 13th and 19th timeframes, the qualified therapist may perform the therapy service visit, reassessment and measurement at any time after the 10th therapy visit but no later than the 13th therapy visit, and after the 16th therapy visit but no later than the 19th therapy visit.

Regarding the access to care concerns, we believe that these requirements will ultimately result in more access to effective therapy services. MedPAC reports broad access to HH care for Medicare beneficiaries. As such, we do not expect that these coverage clarifications will result in access to care issues, but we will monitor for unanticipated effects.

We note, however, because of the volume of comments we received on this issue, we believe that many agencies have not been in compliance with the documentation practices and qualified therapist oversight we would expect. Therefore, we have decided to delay the effective date of these requirements until April 1, 2011, to allow agencies that do not currently have such practices in place additional time to transition.

Comment: A number of commenters expressed support for our efforts to require reassessments, but had questions as to how assessment visit requirements at the 13th and 19th visit would work when multiple therapy disciplines are providing care. Specifically, commenters stated that because HH therapy can consist of any combination of three therapy disciplines, it would be difficult for therapists to track the 13th and 19th visits if more than one therapy discipline was serving the patient. Commenters asked how it would be determined which therapist would do the 13th and 19th assessments. Additionally, commenters were concerned that CMS might be expecting a therapist of one discipline to do the assessment for the therapist of another discipline. Commenters stated that it would be unrealistic and cumbersome to track the 13th and 19th visits, especially when there are multiple therapy disciplines involved. In a related comment, a commenter recommended further clarification of the proposed regulations by requesting that CMS further specify that professional standards should be those pertaining to the individual professions. The commenter also stated that, because existing Medicare regulations require compliance with Federal, State, and local laws, requiring the proposed qualified therapist visits at defined points in the course of treatment could contradict State licensure and scope of practice laws.

Response: We concur with the commenters that we need to clarify our expectation when more than one therapy discipline is providing services to the patient. We will clarify the regulation text to state that the policy applies to each discipline separately. The patient's function must be initially assessed and periodically reassessed by a qualified therapist of the corresponding discipline for the type of therapy being provided (that is, PT, OT, and/or SLP). When more than one therapy discipline is being provided, the corresponding qualified therapist would perform the reassessment during the regularly scheduled visit associated with that discipline which was scheduled to occur as near as possible to the 13th and 19th visit, but no later than the 13th and 19th visit.

We also note that a small percentage of patients which receive 13 and 19 therapy visits receive more than 1 therapy discipline. In addition, HHAs must coordinate their patients' care per longstanding conditions of participation at § 484.14(g). As such, we would expect such coordination to already be occurring. Given the low volume of such patients and the added flexibility as described above, we do not believe that the coordination associated with multi-therapy discipline patients will be overly burdensome. However, we will monitor the effects of this provision to identify unintended consequences.

Comment: Several commenters suggested that instead of putting additional requirements on all HHAs in response to a smaller number of HHAs who are abusing the system, CMS should target those agencies that are providing unnecessary therapy. A few commenters urged CMS to consider how the therapy provisions of this rule would affect HHAs, especially in rural areas, where there is a shortage of therapists. A commenter also stated that the notion that HH expenditures were high due to unnecessary therapy visits is inaccurate and provided statistics that he believes prove therapy overutilization is not a problem.

Response: As we have described in previous comment responses, we believe that these proposed requirements will strengthen the integrity of the benefit while also resulting in better patient outcomes. We believe all HHAs, not just suspect agencies, should adhere to these best practices in order to provide high-quality and effective therapy services, consistent with existing CoPs.

Comment: A few commenters expressed concern regarding therapy services possibly not being covered after a hospitalization, as a result of these assessment visit requirements. Specifically, the commenters were concerned that we were imposing new limits on maintenance therapy. Commenters expressed fear that the result of not covering such therapy services might be that many high fall risk patients would be sent home without therapy care, which would lead to increased falls/hospitalizations/fractures that would increase Medicare spending in the end. Another commenter stated that physical therapy and occupational therapy were utilized more for safety evaluations and fall prevention measures, especially for patients on medication, which places them at a higher risk for falls. This commenter added that fall prevention best practice interventions provided in patients' homes save Medicare money. Similarly, a commenter asked CMS to clarify therapy coverage for pain.

Response: We agree with the commenter that fall prevention practices and/or pain management are essential for many HH patients in order to provide the patient with quality care. We remind the commenter that a longstanding coverage requirement for HH therapy services under Medicare is that the services which the patient needs must require the performance by or supervision of a qualified therapist. Whether or not fall prevention services and pain management services are covered therapy depends on the unique clinical condition of the patient and the complexity of the needed therapy services. Many fall prevention services would not require the skills of a therapist. Longstanding regulations allow therapy coverage when, for safety and effectiveness reasons, the unique medical complexities of the patient require a qualified therapist's skills in the establishment or performance of a therapy maintenance program. As such, should the unique clinical condition of a patient require that the specialized skills, knowledge, and judgment of a qualified therapist are needed to design and establish a safe and effective maintenance program in connection

with a specific illness or injury, then such services would be covered as therapy services.

Comment: Commenters were opposed to the requirement that a skilled nursing service must be needed in order to have maintenance therapy covered, and that a maintenance program cannot be established after restorative therapy has ended.

Response: The intent of language in the proposed rule was to clarify that, in order for the establishment of a maintenance therapy program to be considered covered therapy, the specialized skills, knowledge, and judgment of a therapist would be required in developing a maintenance program. Services would be covered to design or establish the plan, to ensure patient safety, to train the patient, family members and/or unskilled personnel in carrying out the maintenance plan, and to make periodic reevaluations of the plan. In the proposed rule, we further noted scenarios in which maintenance therapy may be provided in the home setting.

The language in the proposed rule was not meant to indicate that maintenance therapy could not be provided as the sole skilled service and would be covered only if ancillary to another skilled qualifying service. The proposed clarifications were not intended to expand or limit existing coverage criteria. We regret the confusion these scenarios may have caused. We note that therapy coverage criteria have always been based on the inherent complexity of the service which the patient needs. As such, maintenance therapy has and will continue to be covered in the HH setting when the unique clinical condition of the patient requires the complex services which can only be provided effectively and safely by a qualified therapist. We will revise the proposed regulation text to address the commenters' confusion.

Comment: A number of commenters expressed concern regarding proposed regulation text changes that state therapy visits would not be covered for transient or easily reversible loss or reduction in function. Some commenters who opposed the proposed regulation text changes stated that these changes would disallow coverage of maintenance therapy, citing longstanding Medicare HH coverage policies previously set out in the "Health Insurance For the Aged, Home Health Agency Manual," Pub. 11 (HIM–11) that allowed for the coverage of such maintenance therapy. One commenter recommended striking the language, "transient and reversible loss." A commenter also stated that these proposed regulation changes are in direct conflict with section 1814(a)(2)(C) of the Act. Commenters questioned what criteria define a transient and reversible reduction in function, or when a patient's condition could be expected to improve spontaneously. One commenter stated that it is difficult to determine when conditions are or are not transient and reversible, noting that some patients who present a very serious condition on admission may recover quickly, while others with seemingly less-serious conditions can end up being far more complex as treatments progress. Another commenter stated we must take into account the patient's unique condition.

Response: We disagree with the commenter that the proposed regulation text changes conflict with section 1814(a)(2)(C) of the Act. We believe that the commenter is inferring that by not allowing therapy coverage for an easily reversible reduction in function, we would be denying coverage to a patient who needs therapy, an eligibility criterion listed in section 1814(a)(2)(C) of the Act. We disagree with such interpretation. Consistent with statute, longstanding regulation, and longstanding manual guidance, therapy coverage under the HH benefit is based on a patient's need for skilled services. The therapy services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified therapist or a qualified therapy assistant under the supervision of a qualified therapist. Services which do not require the performance or supervision of a qualified therapist are not reasonable and necessary services, even if they are performed by a qualified therapist.

When a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, the services do not require the performance or supervision of a qualified therapist, and those services are not considered reasonable and necessary covered therapy services. We acknowledge that making a determination that a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities requires clinical judgment and a consideration of the patient's unique condition. We believe that rehabilitation professionals, by virtue of their education and experience, are typically able to determine when a functional impairment could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Likewise, we expect rehabilitation professionals to be able to recognize when their skills are appropriate to promote recovery. A prescriptive definition of these sorts of conditions, such as a listing of specific disease states that provide subtext for these descriptions is impractical, as each patient's recovery from illness is based on unique characteristics. In response to the commenter who believes that the therapy clarifications would disallow coverage of maintenance therapy, we assure the commenter that these clarifications do not impose new limits on the criteria for maintenance therapy coverage. We again note that therapy coverage criteria have always been based on the inherent complexity of the service which the patient needs. As such, maintenance therapy has and will continue to be covered in the HH setting when the unique clinical condition of the patient requires the complex services, which can only be provided effectively and safely by a qualified therapist. In addition, we note that these clarifications are consistent with longstanding manual guidance.

Comment: A commenter urged CMS to address therapy coverage for conditions that may not directly impact functional status, such as the role of therapists in wound care.

Response: We reiterate that if the services do not require the performance or supervision of a qualified therapist, those services are not considered to be reasonable and necessary covered therapy services. As such, if a therapist (who is qualified to do so per her or his State Practice Act) would perform services such as wound-care, those services would be covered therapy only if they required the skills of the qualified therapist or qualified assistant under the supervision of a qualified therapist. Should a qualified therapist (who is qualified to do so per her or his State Practice Act) perform wound care that does not require the specialized skills of a therapist and could be routinely performed by agency nursing staff, these services would not be covered therapy services.

Comment: A commenter expressed concern over the proposed therapy coverage clarifications, stating that the proposed regulatory text changes are major changes to current policy and that they are in conflict with Medicare statute and current law. The commenter stated that Medicare coverage will be more difficult to obtain for beneficiaries

with chronic and debilitating conditions if the proposals are finalized. The commenter urged CMS to withdraw the maintenance therapy regulation text changes, stating that maintenance therapy is a covered benefit in home health and that Medicare statute does not require improvement for services to qualify for coverage. The commenter stated that the restoration potential of a patient is not the deciding factor in determining whether skilled services are needed, further stating that even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. The commenter stated that a prescribed therapy service which requires the skills of a therapist to help maintain function or prevent slow deterioration is medically necessary and should be covered under the statute. The commenter stated that current regulations recognize this, but the proposed changes minimize this point, and the commenter urged CMS to not restrict benefits in order to fight fraud.

The commenter expressed concern with the proposal's use of the words "improvement" and "progress," fearing an increased emphasis on these terms in the rules for therapy coverage will limit access to care for patients who require maintenance therapy. Further, the commenter alleged that the proposed rule would require improvement for therapy to be covered. The commenter suggested the word "effective" is more appropriate than "improvement" or "progress."

The commenter believed that the proposed regulation text will require the therapist to use complex and sophisticated therapy techniques in order for maintenance therapy to be covered and will thus be a new coverage limitation preventing needed access to therapy, and that the proposed regulation text which states that maintenance therapy must be required in connection with a specific disease would also newly limit maintenance therapy coverage. Further, the commenter alleged that the revised regulation text does not consider the unique condition of the patient as it must and as does the current regulation text. The commenter stated that the proposal newly categorizes maintenance therapy as not rehabilitative, while the current regulations include both restorative and maintenance therapy as rehabilitative. The commenter stated that, should CMS require improvement as a therapy coverage criterion, CMS would be applying an arbitrary "rule of thumb" which does not consider the patient's individual condition, and such a requirement for improvement conflicts with the current regulation at § 409.42. Further, the commenter stated that the proposed regulation text changes will result in denials of Medicare coverage for beneficiaries with long-term, progressive, or incurable conditions. The commenter also took issue with the proposed regulation text change to require the documentation of progress toward goals.

The commenter further stated that the definition of maintenance therapy is too vague and restrictive. The commenter also took issue with the proposed regulation text, which requires that, in order for maintenance therapy to be covered, the skills of a therapist must be needed to ensure the patient's safety "and" the skills of a therapist are needed to provide a safe and effective maintenance program. The commenter believed that we should replace the "and" with an "or". The commenter also stated that the regulation does not define "reasonable and necessary" in a way that clearly provides for coverage of maintenance therapy. As was also mentioned by other commenters, this commenter was concerned that the proposed regulation text describes coverage of the development of a maintenance program during the last visit(s) for rehabilitative therapy, stating that, often, standard practice is to establish and instruct the patient in an appropriate maintenance program at the outset of a course of therapy. The commenter also spoke to the proposed regulation text change, which appears to indicate that we would not cover the establishment of a maintenance program after a restorative therapy program has ended, or if a beneficiary had never met the criteria for restorative therapy. The commenter stated that the proposed regulation text would result in maintenance therapy becoming a dependent service.

Response: The proposed regulatory text clarifications are intended to neither limit nor expand the coverage of therapy in the HH setting, but instead are intended to provide clear therapy guidelines, as suggested by MedPAC, to deter inappropriate provisions of therapy services. As we have described in earlier responses to comments, we also believe that these guidelines will improve patient outcomes, improve therapy effectiveness, and promote more consistent compliance with the Medicare CoPs. However, as we described in an earlier comment response, we agree with the commenter that the proposed regulation text changes may have been unclear in the descriptive scenarios surrounding coverage of the development of a maintenance program, and we will revise the final regulation text changes at § 409.44(c)(2)(iii)(B) to remove the scenarios described in the proposed rule's § 409.44(c)(2)(iii)(B)(1) through (B)(3).

We also agree with the commenter that there are some additional changes to the proposed regulation text that we should finalize for better clarity. We believe that these changes may alleviate some of the commenter's concerns that the proposed rule limits coverage associated with maintenance therapy, and reassure the commenter that the coverage criteria clarifications are consistent with statute, current regulations, and longstanding manual guidance. Specifically, in response to the commenter's concern that we would have newly categorized maintenance therapy as non-rehabilitation, we will delete the proposed regulation text at § 409.44(c)(2)(iii)(A)(2) and (A)(3) for the final rule. We believe our attempts to clarify these definitions are not needed, as those definitions are well defined in § 409.44(c)(2)(iii)(A) through (iii)(C). We will also finalize some technical changes to the proposed regulation text, including replacing several of the proposed regulatory text references to improvements in function with references to the effectiveness of the care plan goals, as suggested by the commenter.

We agree with the commenter that that current regulations and longstanding manual guidance are consistent in that therapy services are covered in the HH setting based on the inherent complexity of the service which the patient needs. As such, maintenance therapy has and will continue to be covered in the HH setting when the unique clinical condition of the patient requires the complex services, which can only be provided effectively and safely by a qualified therapist.

Regarding the commenter's concern that the proposed rule stated that skilled therapy is not reasonable and necessary unless improvement is documented, we disagree with the commenter's interpretation of the proposed rule. However, we agree that we could have been more clear in the regulation text which describes the documentation requirements at § 409.44(c)(2)(i). In the final rule, we will clearly state that maintenance therapy as defined in § 409.44(c)(2)(iii)(B) and § 409.44(c)(2)(iii)(C) would not be subject to the criteria listed in § 409.44(c)(2)(i)(B)(4).

Concerning the comment that the proposed regulation text, which requires the therapist to use complex and

sophisticated therapy techniques in order for maintenance therapy to be covered, imposes a new coverage limitation associated with maintenance therapy and will prevent needed access to therapy, we refer the commenter to longstanding manual guidance at 40.2.2 E. in chapter 7 of the Medicare Benefit Policy Manual, CMS Pub. 100–2. This section contains longstanding guidance which uses the term "complex and sophisticated procedures" when describing reasonable and necessary maintenance therapy. This same chapter instructs a reviewer to consider the inherent complexity of the service when determining if the skills of a therapist are required. The complexity and sophistication of the service are longstanding criteria used to assess whether the skills of a therapist are required. As such, we disagree with the commenter that this is a new limiting criterion. We also disagree that the proposed regulation text changes do not adequately consider the unique condition of the patient when clarifying coverage requirements. In fact, we believe the proposed regulation text changes at § 409.44(c)(2)(iii) refer more comprehensively than the current regulation text to the patient's unique clinical condition as a criterion for determining whether the complex services which must be provided by a therapist are needed. Regarding the commenter's concern that the proposed regulation text changes newly require that maintenance therapy must be needed in connection with a specific disease, we also disagree. Current regulations at § 409.44(c)(2)(iii) describe that establishing a maintenance program would be covered if the skills of a therapist are needed to provide a safe and effective maintenance program in connection with a specific disease. However, we agree that the words "in connection with the patient's illness or injury" instead of "in connection with a specific disease" would be an improvement to the regulation text and we are making this change in this final rule. We disagree with the commenter that current policy allows maintenance therapy to be covered when the skills of a therapist are needed to ensure the patient's safety OR the skills of a therapist are needed in order to provide a safe and effective maintenance program. We have required in regulation and longstanding manual guidance that the skills of a therapist would be required to ensure both patient safety and effectiveness of a maintenance program for the performance of maintenance therapy to be covered.

We refer the commenter to current regulations at § 409.44(c)(2)(iii) and longstanding manual guidance at 40.2.2 E. in chapter 7 of the Medicare Benefit Policy Manual, CMS Pub. 100–2. Regarding the commenter's concern that current § 409.32(c) mandates the restoration potential of a patient is not the deciding factor in determining whether skilled services are needed, and even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities, we reply that we believe the commenter may be misunderstanding the current regulation text at § 409.32(c) or interpreting this out of its proper context. We believe it is important to again note that the emphasis for our therapy coverage criteria is not on the issue of restoration potential per se, but rather on the beneficiary's need for complex services which require the skills of a qualified therapist. Current regulations at § 409.32(c) specify that it is the beneficiary's need for *skilled services* rather than his or her restoration potential that is the deciding factor in evaluating the need for skilled nursing services in the HH setting. A beneficiary's restoration potential has never been a factor at all in identifying those services that constitute skilled *nursing* care. Thus, nursing care can be considered skilled without regard to whether it serves to improve a beneficiary's condition or to maintain the beneficiary's current level of functioning. In fact, as the original version of this regulation's text [as initially codified at 20 CFR § 405.127(b)(2) (40 FR 43897, September 24, 1975)] makes clear, this provision's example of a terminal cancer patient was intended to refer specifically to *nursing* services that can be considered skilled "even though no potential for *rehabilitation* exists" (emphasis added). Longstanding current regulatory language at § 409.44(c) sets out the criteria for skilled therapy (as opposed to the skilled nursing criteria described above) to be a covered service under Medicare's HH benefit. Current regulations specify that HH therapy services are covered based on the inherent complexity of the service which the patient needs, and whether the needed services require the skills of a qualified therapist. Further, current regulations state that HH therapy services are covered if there is an expectation that the patient's condition will improve in a reasonable and predictable timeframe based on the physician's assessment of the beneficiary's restoration potential and unique medical condition of the patient. Current regulations also allow for therapy coverage when, for safety and effectiveness, the unique medical complexities of the patient require a qualified therapist's skills in the establishment or performance of a therapy maintenance program.

Regarding the commenter's concerns that, should we require improvement as a therapy coverage criteria, we would be applying an arbitrary "rule of thumb" which does not consider the patient's individual condition, and as such, the requirement conflicts with the current regulation at § 409.44, we again assure the commenter that we are not expanding or limiting the coverage of HH therapy. To address the commenter's concerns regarding the potential for claims denials based on "rules of thumb," we assure the commenter that such denials are prohibited.

"Rules of thumb" in the Medicare medical review process are prohibited. Intermediaries must not make denial decisions solely on the reviewer's general inferences about beneficiaries with similar diagnoses or on general data related to utilization. Any "rules of thumb" that would declare a claim not covered solely on the basis of elements, such as, lack of restoration potential, ability to walk a certain number of feet, or degree of stability, is unacceptable without individual review of all pertinent facts to determine if coverage may be justified. Medical denial decisions must be based on a detailed and thorough analysis of the beneficiary's total condition and individual need for care.

Similar instructions have appeared as far back as 1992 in the previous, paper-based manuals (available online at *http://www.cms.gov/Manuals/PBM/list.asp*), in section 3900.A of the Medicare Intermediary Manual, Part 3 (CMS Pub. 13–3), and in section 214.7 of the Medicare SNF Manual (CMS Pub. 12).

Regarding the comment that the proposed regulation does not define "reasonable and necessary" in a way that clearly provides for coverage of maintenance therapy, we believe the commenter took issue with proposed clarifications surrounding regulations at § 409.44(c)(2)(iv) which state that the amount, frequency, and duration of services must be reasonable. In these revisions we describe that therapy can be considered reasonable and necessary when the criteria for maintenance therapy are met. We believe the commenter suggests we more definitively state that therapy would be

covered in such a case. We concur, and we will make this change.

Comment: One commenter noted that under a state's approved Medicaid State Plan Amendment, therapies may be authorized as appropriate to maintain function or to slow the rate of decline in function. This commenter therefore requested that we consider whether the proposed rule language should be revised to clarify a potential difference in benefits [under Medicaid versus Medicare] or if revised instructions regarding Conditions of Participation (CoPs) applicability is sufficient. For whatever option we choose, this commenter indicated that we should contemplate using the Medicare rules as the foundation for Medicaid HH program rules as this commenter believes that changes are needed to accommodate the permitted differences in benefits.

Response: We thank the commenter but note such a suggestion is outside the scope of this rule, and the issue for which we solicited comments. We will consider this suggestion in the future as we analyze improvements to the HH PPS.

Comment: Commenters stated that, while they applaud our efforts to better define medical necessity and document therapy services, they were also concerned that the new documentation requirements will be a difficult transition for HHAs, stating that the proposed requirement would require significant time and resources for HHAs to ensure that their therapists and other medical staff are educated and prepared to implement the new requirements into their everyday practices. Consequently, this commenter recommended we provide extensive educational outreach and the commenter asked that we delay implementation of these requirements to provide agencies time to retrain staff.

This commenter also recommended that we elaborate further on provisions of the proposed § 409.44(c)(1), including citing references to resources we used for the phrase "with accepted standards of clinical practice," asking us to indicate that these included resources from professional associations. In addition, this commenter asked that we indicate that the "therapy goals" be established by the qualified therapist in conjunction with the physician. This commenter also requested that we further clarify what we mean by objective measurement of therapy progress by including activities of daily living such as walking, eating, bathing, etc. With respect to § 409.44(c)(2)(i), this commenter asked that we clarify what are considered to be "accepted practice" and "effective treatment." Similar to other commenters, this commenter requested that we further acknowledge multi-therapy cases and insert language that allows for some type of window for completing the reassessment prior to or after the 13th or 19th therapy visits, stating that the adjustment should be made to account for extenuating circumstances that are outside the control of the qualified therapist. Regarding assistants making clinical notes, this commenter suggested that we change the phrase "job title" to "professional designation" and clarify that written and electronic signatures are acceptable. Some commenters asked that we eliminate § 409.44(c)(2)(i) altogether. Regarding § 409.44(c)(2)(iii), this commenter requested that because "rehabilitative" and "restorative" are not interchangeable, we change our regulations to be consistent throughout, using only the word "rehabilitative." This commenter also asked that we add a sentence to clearly state that the maintenance program must be established by the qualified therapist. With respect to § 409.44(c)(2)(iv), this commenter asked that we elaborate on the phrase "with accepted standards of clinical practice" and highlight the importance of educating caregivers to ensure patients receive the appropriate level of care. The commenter also requested that we delay implementation of these requirements until April 2011 to allow time for providers to transition.

Response: We thank the commenter for the suggested clarifications and we have adopted the suggested clarifications with some exceptions. We have retained the language in our current regulatory text at § 409.44(c)(2)(iii) which presently mandates that for therapy to be covered, there must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and medical condition. Typically, we use the term "rehabilitative" to describe services provided by therapists. In the regulation text, we describe the physician's assessment and therefore we believe the "restorative" terminology is appropriate. However, we will finalize additional changes to the proposed regulation text to achieve more consistency in the usage of these terms. As described in an earlier comment, we have adopted the commenter's request for flexibility associated with the 13th and 19th visit. We believe that clarifications regarding electronic signatures are better addressed in manual guidance. Finally, we will implement this provision beginning April 2011.

Comment: Some commenters urged CMS to transform the HH PPS therapy reimbursement model to one based on clinical outcomes and skill improvement. A commenter urged CMS to adopt tests for clinicians, which assess the clinician's abilities.

Response: We thank the commenter for these suggestions. As we described in earlier comment responses, section 3131(d) of the Affordable Care Act requires CMS to conduct a study on costs involved with providing HH services for patients with high severity of illness, including analysis of potential revisions to outlier payments to better reflect costs of treating Medicare beneficiaries and analyze other HH PPS issues determined by the Secretary. We intend to use this opportunity to assess a variety of HH PPS issues, including our current HH PPS therapy threshold reimbursement.

Comment: A commenter suggested that CMS consider making access to physician-ordered medically necessary music therapy as a covered service.

Response: We thank the commenter but note that Congress would need to enact legislation in order to cover music therapy services under Medicare's HH benefit, as they are not currently covered HH services as defined in section 1861(m) of the Act.

Comment: Commenters provided feedback regarding our plans to revise G-codes to reflect greater detail in the reporting of skilled nursing and therapy services. Many commenters requested more time (6 months to a year or more) be allowed before these new and revised codes become effective, so as to give more time for CMS to provide direction to HHAs and thus provide time for agencies to train staff and modify data collection systems to accommodate these coding changes. Another commenter questioned the lead-time to establish new G-codes, stating that it would be impossible for all necessary program changes to be made to all vendor software within three months. This commenter requested that CMS postpone the new and revised G-codes until 2012 to give agencies and vendors time to reprogram the requirements. The commenter also suggested that the types of descriptions of the codes identified suggest that CMS wants to use the codes to determine medically reasonable and necessary care rather than doing actual medical review of patient clinical records. The commenter noted that 60 to 75 percent of claims in which the appeals are taken to the administrative law judge level are reversed and suggested that we already have an issue

with our medical review and program integrity units that would be further exacerbated by the proposed G-codes.

Response: It is important to note that we provided the information on the new G-codes to the industry as a pre-notification of our intention to collect additional information on the claim. The implementation of this provision will be issued in an administrative change notice. We note that in describing our plans in the proposed rule published on July 23, 2010, we intended to provided the industry with early information so that they could begin planning for this change at that time. We currently plan to implement this reporting requirement in January 2011. However, we thank the commenter, and we will consider this suggestion.

Comment: Commenters expressed concern regarding G-code 6, stating that it has combined two dissimilar activities and should be split to avoid confusion, resulting in possible erroneous data. Specifically, commenters indicated that a G-code for services for the management and evaluation of the plan of care should be separate from a G-code for the services for the observation and assessment of a patient's condition while a patient's treatment is stabilized.

Response: We concur with this suggestion and will adopt the separate G-codes.

Comment: Some commenters asked that in revising and adding G-codes for the reporting of HH services, CMS should also consider creating codes to differentiate between the services provided by a registered nurse (RN) and a licensed practical nurse (LPN).

Response: We thank the commenters for this suggestion and will consider their recommendation in future rulemaking.

In summary, we thank the many commenters for their thoughtful and comprehensive suggestions. After considering these comments, we will finalize the proposed therapy coverage clarifications with several changes. We will delay the implementation of the therapy provisions until April 1, 2011, to allow agencies more transition time. We will finalize exceptions to the 13th and 19th qualified therapy visit requirement to provide some flexibility associated with patients in rural areas, patients receiving more than 1 therapy discipline, and documented exceptional circumstances which would preclude the therapist from performing the needed 13th or 19th visit. We have made regulatory text changes to remove confusing scenarios associated with maintenance therapy, which led commenters to believe that maintenance therapy was a dependent service. We will finalize numerous other regulation text changes to clarify that these changes do not impose new limitations on the coverage of maintenance therapy. The changes include clarifications that when the criteria for maintenance therapy is met, a qualified therapist would be assessing the effectiveness of the therapy provided, rather than the patient's progress. Other changes include the removal of definitions of rehabilitative therapy which was confusing to commenters, and other miscellaneous regulation text clarifications which were suggested and we believe improve the clarity of the regulation text.

C. Outlier Policy

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient HH care needs. Prior to the enactment of the Affordable Care Act in March 2010, this section stipulated that total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. Under the HH PPS, outlier payments are made for episodes for which the estimated costs exceed a threshold amount. The wage adjusted fixed dollar loss (FDL) amount represents the amount of loss that an agency must absorb before an episode becomes eligible for outlier payments. As outlined in our FY 2000 HH PPS final rule (65 FR 41188 through 41190), Medicare provided for outlier payments not to exceed 5 percent of total payments and adjusted the payment rates accordingly.

2. Regulatory Update

In our November 10, 2009 HH PPS final rule for CY 2010 (74 FR 58080 through 58087), we explained that our analysis revealed excessive growth in outlier payments in discrete areas of the country. Despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures exceeded the 5 percent statutory limit. Consequently, we assessed the appropriateness of taking action to curb outlier abuse.

In order to mitigate possible billing vulnerabilities associated with excessive outlier payments, and to adhere to our statutory limit on outlier payments, we adopted an outlier policy of an agency-level cap on outlier payments at 10 percent of the agency's total payments, in concert with a reduced FDL ratio of 0.67. This policy resulted in a projected target outlier pool of approximately 2.5 percent (the previous outlier pool target was 5 percent of total HH expenditures). For CY 2010, we first returned 5 percent back into the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool targeted to 2.5 percent. This revised outlier policy was adopted for CY 2010 only.

3. Statutory Update

Section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, "Adjustment for outliers," to state, "The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to HH services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to 5 percent of the total payments estimated to be made based on the prospective payment system under this subsection for the period." In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising it to state that the Secretary, "may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph with respect to a fiscal year or year may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year." As such, our HH PPS outlier policy must reduce payment rates by 5 percent, and target up to 2.5 percent of total estimated HH PPS payments to be paid as outlier payments. We will first return the 2.5 percent held for the target CY 2010 outlier pool to the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We will then reduce these rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years, the total amount of the additional payments or payment adjustments made may not exceed 2.5 percent of the total payments projected

or estimated to be made based on the PPS in that year as required by section 1895(b)(5)(A) of the Act as amended by section 3131(b)(2)(B) of the Affordable Care Act.

4. Outlier Cap

As stated earlier, for CY 2010, we implemented an agency-level cap by limiting HH outlier payments to be a maximum of 10 percent of an agency's total payments (74 FR 58080 through 58087). Section 3131(b)(2)(C) of the Affordable Care Act makes this 10 percent agency-level cap a permanent statutory requirement, by adding a paragraph, (B) "Program Specific Outlier Cap", to section 1895(b)(5) of the Act. The new paragraph states, "The estimated total amount of additional payments or payment adjustments made * * * with respect to a HHA for a year (beginning with 2011) may not exceed an amount equal to 10 percent of the estimated total amount of payments made under this section (without regard to this paragraph) with respect to the HH agency for the year". Therefore, the 10 percent agency-level outlier cap would continue in CY 2011 and subsequent calendar years as required by section 1895(b)(5)(B) of the Act, as added by section 3131(b)(2)(C) of the Affordable Care Act. In summary, section 3131(b) of the Affordable Care Act requires the following outlier policy: (1) Reduce the estimated total payments by 5 percent; (2) target to pay no more than 2.5 percent of estimated total payments for outliers; and (3) apply a 10 percent agency-level outlier cap.

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

The July 2000 final rule (65 FR 41189) described a methodology for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated cost exceeds a threshold amount. The payment rate for a 60-day episode is the sum of the wage-adjusted national per-visit rate amounts for all visits delivered during the episode. The outlier threshold is defined as the sum of the episode payment rate for that case-mix group and a FDL amount. Both components of the outlier threshold are wage-adjusted. The wage-adjusted FDL amount represents the amount of loss that an agency must experience before an episode becomes eligible for outlier payments. The wage-adjusted FDL amount is computed by multiplying the national standardized 60-day episode payment amount by the FDL ratio, and wage-adjusting that resulting amount. The wage-adjusted FDL amount is then added to the wage-adjusted 60-day episode payment rate to arrive at the wage-adjusted outlier threshold amount.

The outlier payment is defined as a proportion of the wage-adjusted estimated costs beyond the wage-adjusted outlier threshold amount. The proportion of additional costs paid as outlier payments is referred to as the loss-sharing ratio. Prior to the passage of the Affordable Care Act, the FDL ratio and the loss-sharing ratio were selected so that the estimated total outlier payments would not exceed the 5 percent aggregate level. We chose a value of 0.80 for the loss-sharing ratio, which is relatively high, but preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional costs above the wage-adjusted outlier threshold amount. A loss-sharing ratio of 0.80 is also consistent with the loss-sharing ratios used in other Medicare PPS outlier policies, such as inpatient hospital, inpatient rehabilitation, long-term hospital, and inpatient psychiatric payment systems.

As discussed in the October 1999 proposed rule (64 FR 58169) and the July 2000 final rule (65 FR 41189), the percentage constraint on total outlier payments creates a tradeoff between the values selected for the FDL ratio and the loss-sharing ratio. For a given level of outlier payments, a higher FDL ratio sets higher FDL amounts and thus reduces the number of cases that receive outlier payments, but allows for setting a higher loss-sharing ratio and higher outlier payments per episode. Alternatively, a lower FDL ratio means lower FDL amounts and therefore allows more episodes to qualify for outlier payments but setting a lower loss-sharing ratio and lower outlier payments per episode.

Therefore, setting these two parameters (that is, FDL ratio and loss-sharing ratio) involves policy choices about the number of outlier cases and their payments. In the CY 2010 HH PPS final rule (74 FR 58086), in targeting total outlier payments as 2.5 percent of total HH PPS payments, we implemented a FDL ratio of 0.67.

For this rule, we have updated our analysis from the CY 2010 HH PPS final rule and we estimate that maintaining a FDL ratio of 0.67, in conjunction with a 10 percent cap on outlier payments at the agency level, would target paid outlier payments to be no more than the 2.5 percent of total HH PPS payments as required by section 1895(b)(5)(A) of the Act, as amended by section 3131(b)(2)(B) of the Affordable Care Act.

The following is a summary of the comments we received regarding the outlier payment policy.

Comment: A commenter supported CMS in its efforts to curb fraud and abuse in the Medicare program. The commenter is not opposed to the proposed implementation of these changes to the outlier policy. However, the commenter cautioned CMS to carefully analyze the effect this outlier policy might have on HHAs in rural and underserved areas. Often times, patients who are sicker and more clinically complex may be treated in the HH setting due to lack of access to other post-acute care settings. HHAs treating such patients would have higher outlier costs than HHAs that are located in urban and higher socioeconomic areas. The commenter strongly urged CMS to ensure that these HHAs were not unfairly audited or penalized for the treatment furnished to these patients. Another commenter stated that some remote rural areas have only one agency per county and many counties have no HHAs. In such rural areas, there would be no other agency to share intake of clients who have costly outlier episodes. State regulations for Medicaid or assisted living programs could force clients to be admitted to a nursing home because agencies in these remote rural markets might not be able to afford to provide care for them. The commenter further urges that small HHAs (that is, those with fewer than 300 patients) in remote rural areas should be exempt from the agency-level outlier cap or have a higher cap. Another commenter recommended exempting agencies with fewer than 60 Medicare patients per year from the outlier policy since even one or two outlier episodes could easily reach the cap. This policy could force some small HHAs to refuse care to patients who are most in need of care.

Response: We will take these comments into consideration when we conduct our study on costs involved with providing ongoing access to HH services for patients with high severity of illness, as required by the Affordable Care Act.

Comment: Several commenters stated that the proposed outlier policy is unfair because all agencies are held accountable for the unscrupulous behavior of a few agencies. The commenters believed that CMS is taking a broad stroke approach to implementing changes that could be detrimental to the many agencies that are operating appropriately and in compliance with the regulations. A commenter stated that the outlier policy would further reduce patient access and would fail to target the abusers. Several

commenters stated that the legislative limit placed on the outlier pool would punish all agencies for the outlier policy abuse of a very limited number of agencies. Several commenters recommended restoring the 2.5 percent reduction to the payment rates. Another commenter stated that the proposed cut of 2.5 percent to the base payment for all HHAs in order to "pay" for this policy was unfair and excessive, especially considering other proposed cuts. The commenter recommended that CMS limit any single year rate reductions including statutory reductions and case-mix change adjustments to no greater than an aggregate 2.5 percent. Another commenter noted that the Affordable Care Act mandated that the reduction in payments for outliers be 5 percent and that the outlier target be 2.5 percent of total payments. As the difference of 2.5 percent remains unallocated in the proposed rule, the commenter suggested that CMS redesignate that difference to the proposed 3.79 percent decrease for case-mix change, resulting in a case-mix adjustment of 1.29 percent decrease. Otherwise, the CY 2011 HHA rate will be hit twice—by the 3.79 percent case-mix decrease and the 2.5 percent outlier pool decrease. Another commenter stated that HHAs have already sustained a significant cut in outlier payments, leaving insulin dependent and wound care patients without a nurse to provide injections and necessary wound care treatment. At any given time, an agency cannot assess whether it has the resources to accept these types of patients. A commenter requested that CMS exempt "special needs" HHAs that serve high-cost patients with multiple clinical issues from the 10 percent agency-level outlier cap. The commenter believed a revision to a higher outlier cap is critical for continued provision of care by agencies serving high-need and high-cost beneficiaries without losing critical outlier funding.

Response: Section 3131(b) of the Affordable Care Act does not allow for exceptions to the mandate of the outlier policy which reduces estimated aggregate HH payments by 5 percent, allows no more than an estimated 2.5 percent of aggregate HH payments to be outlier payments, and requires the 10 percent agency-level outlier cap. We do not have regulatory authority to restore the 2.5 percent to the estimated aggregate HH payments. Nonetheless, we will continue to monitor outlier payments in order to advise the legislators of any unintended consequences of this legislation, such as lack of access to care.

Comment: A commenter stated that he interpreted Table 4 in the July 23, 2010 proposed rule (75 FR 43257) to indicate that each year HHAs can expect an additional 2.5 percent reduction to the base episode rate starting from the prior year's base rate before the market basket update. This additional rolling reduction does not seem contemplated in the Affordable Care Act. A commenter stated that the 2.5 percent rate reduction combined with the standard 3 percent inflation/cost of living increases demanded by their employees will result in their agency being unable to hire staff to serve their patients. CMS does not identify actual outlier payment history when addressing these changes in the rule.

Response: The 2.5 percent reduction is not a rolling reduction. The 2.5 percent reduction is a one-time, but permanent, reduction to the HH rates, which is to be applied in CY 2011.

Table 3 shows outlier payment history as a percentage of total HH PPS payments between CY 2004 and CY 2008.

TABLE 3—OUTLIER PAYMENT HISTORY AS A PERCENTAGE OF TOTAL HH PPS PAYMENTS

[Between CY 2004 and CY 2008]

Year	Outlier payment	Total HH PPS payment	Percentage change
2004	$309,198,604	$11,500,462,624	2.69
2005	527,096,653	12,885,434,951	4.09
2006	701,945,386	14,041,853,560	5.00
2007	996,316,407	15,677,329,001	6.36
2008	1,127,162,152	17,114,906,875	6.59

Comment: A commenter stated that the outlier policy will significantly decrease fraudulent behavior within the Miami-Dade, Florida area. The commenter further supports more open dialogue between the HH community and government officials to improve program integrity within the Medicare program.

Response: We appreciate the comment and the commenter's support.

6. Imputed Costs

Section 3131(d) of the Affordable Care Act requires CMS to conduct a study on costs involved with providing HH services for patients with high severity of illness, including analysis of potential revisions to outlier payments to better reflect costs of treating Medicare beneficiaries. CMS will produce a Report to the Congress containing this study's recommendations no later than March 1, 2014.

To consider outlier policy improvements in the nearer term, we solicited comments regarding alternate policy options and methodologies to better account for high cost patients. In particular, we solicited the industry's input on alternatives in imputing costs in the calculation of the outlier payments.

We have discussed and are exploring the possible use of visit intensity data in the imputing of costs as part of the outlier payment calculation and would be interested in the industry's views on such an alternative. In addition, we solicited feedback concerning the use of diagnoses codes (for example, diabetes) as a factor in the calculation of imputed costs associated with outlier payments. We believe that modifying the fixed dollar loss ratio or the loss-sharing ratio now would not improve the current policy. However, we welcome industry comments on such potential modifications.

The following is a summary of the comments we received regarding imputed costs.

Comment: Several commenters stated that visit intensity data or diagnoses are not the only issues impacting outliers. CMS should consider a comprehensive look at resource utilization which might include these factors. Another commenter stated that the proposed rule does not specify how "visit intensity" is to be measured, such as whether the length of the visit or the frequency of visits would be measured. Several commenters stated that in addition to intensity data and diagnoses, resource

utilization, and other factors affect costs for an outlier episode and should be taken into consideration.

Another commenter suggested using actual, inflation-adjusted, agency-specific costs for each discipline rather than the imputed LUPA rates currently used to calculate the outlier payment. Calculations using such costs would reduce abuse by agencies that game the system by providing excessive numbers of visits at visit costs below the LUPA rate. Using actual costs versus imputed costs would better estimate the needs of patients who are severely impaired. Continued use of imputed costs to administer the outlier leaves the program vulnerable to abuse while simultaneously compromising the usefulness of the outlier costs concept for seriously ill patients of reputable agencies.

Response: We appreciate these comments and will take them into consideration when we conduct a study of outlier payments required by the Affordable Care Act. We will produce a Report to the Congress containing this study's recommendations no later than March 1, 2014.

D. CY 2011 Rate Update

1. Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2011 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. Section 3401(e) of the Affordable Care Act amended section 1895(b)(3)(B) of the Act by adding a new clause (vi) which states, "After determining the HH market basket percentage increase * * * the Secretary shall reduce such percentage * * * for each of 2011, 2012, and 2013, by 1 percentage point. The application of this clause may result in the HH market basket percentage increase under clause (iii) being less than 0.0 for a year, and may result in payment rates under the system under this subsection for a year being less than such payment rates for the preceding year."

The following is a summary of the comments we received regarding the HH market basket update.

Comment: A commenter believes that the market basket index fails to include consideration of the direct cost increases that CMS rules may have on the delivery of care. Instead, the index evaluates general cost changes such as the cost of caregivers, transportation, insurance, and office space. This approach does not provide CMS with sufficient information to adjust payment rates in relation to regulatory cost increases.

When the HH services "product" changes because of new regulatory requirements, CMS should include in the market basket index an element to address the resulting cost changes. Alternatively, CMS should adjust base payment rates to account for such cost changes as done previously for costs associated with OASIS.

Response: The HH market basket is not designed to account for changes in total costs (such as those associated with the implementation of OASIS–C or other initiatives), but is rather intended to measure the input price pressures that the average HH provider is expected to face in the coming year.

The composition of the market basket itself is made up of a set of mutually exclusive and exhaustive cost categories that reflect the cost structure of the industry (in a given base year). The HH index's cost shares (or weights) are based on data reported on the Medicare cost report forms and are specific to HHAs. Each cost category is assigned an appropriate price proxy whose projected movements are weighted by their respective cost shares and aggregated to arrive at the actual market basket update.

Any cost increases that a provider bears based on regulatory requirements must be reflected in the increasing costs of the inputs on provision of the service. When the market basket is rebased, cost changes will be accounted for in the data, up to and including the base year. We evaluate the cost weight distributions on a periodic basis. If the cost structure of the HH industry changes, such as a greater share of expenses being devoted to wages and salaries, we will propose to rebase and revise the market basket, as appropriate.

Comment: A commenter states that the continued reductions to the home health market basket update each year for 2011, 2012, and 2013 are drastic. These cuts come at a time when labor costs—particularly nurses and therapist—continue to rise.

Response: Since publication of the CY 2011 HH PPS proposed rule, we have updated the HH market basket increase for CY 2011. The updated HH market basket increase is 2.1 percent, which is based on IHS Global Insight Inc.'s third quarter 2010 forecast, utilizing historical data through the second quarter of 2010. A detailed description of the methodology used to derive the HH market basket is available in the CY 2008 HH PPS proposed rule (72 FR 25356, 25435). Due to the new requirement at section 1895(b)(3)(B)(vi) of the Act, the CY 2011 market basket update of 2.1 percent must be reduced by 1 percentage point to 1.1 percent. In effect, the CY 2011 market basket update is 1.1 percent. The statute does not permit us to exercise any discretion with respect to the application of this percentage point reduction.

2. Home Health Care Quality Improvement

a. OASIS

Section 1895(b)(3)(B)(v)(II) of the Act requires that "each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause." In addition, section 1895(b)(3)(B)(v)(I) of the Act dictates that "for 2007 and each subsequent year, in the case of a HHA that does not submit data to the Secretary in accordance with sub clause (II) with respect to such a year, the HH market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points." This requirement has been codified in regulations at § 484.225(i).

Accordingly, for CY 2011, we will continue to use a HHA's submission of OASIS data to meet the requirement that the HHA submit data appropriate for the measurement of health care quality. For CY 2011, we proposed to consider OASIS assessments submitted by HHAs to CMS in compliance with HHA Conditions of Participation for episodes beginning on or after July 1, 2009 and before July 1, 2010 as fulfilling the quality reporting requirement for CY 2011. This time period allows for 12 full months of data collection and would provide us the time necessary to analyze and make any necessary payment adjustments to the payment rates in CY 2011. We will reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements in CY 2011 and each year thereafter on an annual cycle July 1 through June 30 as described above.

As set forth in the CY 2008 final rule, agencies do not need to submit quality data for those patients who are excluded from the OASIS submission requirements under the Home Health Conditions of Participation (CoP) (§ 484.200 through 484.265), as well as those excluded, as described in the Final Rule Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for

Home Health Agencies December 23, 2005 (70 FR 76202) as follows:

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

As set forth in the CY 2008 final rule (72 FR 49863), agencies that become Medicare-certified on or after May 1 of the preceding year (2010 for payments in 2011) are excluded from any payment penalty for quality reporting purposes for the following CY. Therefore, HHAs that are certified on or after May 1, 2010 are excluded from the quality reporting requirement for CY 2011 payments. These exclusions only affect quality reporting requirements and do not affect the HHA's reporting responsibilities under the CoP. HHAs that meet the quality data reporting requirements would be eligible for the full HH market basket percentage increase. HHAs that do not meet the reporting requirements would be subject to a 2 percent reduction to the HH market basket increase in conjunction with applicable provisions of the Affordable Care Act, as discussed in the section II.X. of this final rule "CY 2011 Payment Update."

Section 1895(b)(3)(B)(v)(III) of the Act further requires that "[t]he Secretary shall establish procedures for making data submitted under sub clause (II) available to the public. Such procedures shall ensure that a HHA has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public." We will continue to use the subset of OASIS data that is utilized for quality measure development and publicly reported on Home Health Compare as the appropriate measure of HH quality.

To meet the requirement for making such data public, we will continue to use the Home Health Compare Web site, which lists HHAs geographically. Currently, the Home Health Compare Web site lists 12 quality measures from the OASIS data set as described later. The Home Health Compare Web site, which is scheduled to be redesigned this Fall is located at *http://www.medicare.gov/HHCompare/Home.asp.* Each HHA currently has pre-publication access, through the CMS contractor, to its own quality data, as the contractor updates this periodically. We will continue this process, to enable each agency to view its quality measures before public posting of data on Home Health Compare Web site.

The following 12 outcome measures are currently publicly reported:

- Improvement in ambulation/locomotion;
- Improvement in bathing;
- Improvement in transferring;
- Improvement in management of oral medications;
- Improvement in pain interfering with activity;
- Acute care hospitalization;
- Emergent care;
- Discharge to community;
- Improvement in dyspnea;
- Improvement in urinary incontinence;
- Improvement in status of surgical wounds; and
- Emergent care for wound infections, deteriorating wound status.

We will continue to use specified measures derived from the OASIS data for purposes of measuring HH care quality. This would also ensure that providers would not have an additional burden of reporting quality of care measures through a separate mechanism, and that the costs associated with the development and testing of a new reporting mechanism would be avoided.

We have changed the set of OASIS outcome measures that will be publicly reported beginning in July 2011 to include the following outcome measure:

- Increase in number of pressure ulcers.

This outcome measure is the percentage of patient episodes in which there was an increase in the number of unhealed pressure ulcers. This measure is important because pressure ulcers are key indicators of the effectiveness of care and are among the most common causes of harm to patients. Though consensus endorsement is not a requirement for public reporting of HH quality measures, this measure is endorsed by the National Quality Forum (NQF).

As previously stated, although NQF endorsement is not required for public reporting, we will discontinue public reporting of certain outcome measures, which were previously reported on Home Health Compare and are no longer endorsed by NQF. Those measures are the following:

- Discharge to community;
- Improvement in Urinary Incontinence; and
- Emergent Care for Wound Infections, Deteriorating Wound Status.

We solicited comments on these measures in the CY 2011 HH PPS proposed rule.

Additionally, the change to OASIS–C results in modifications to two of the outcome measures as follows:

- Improvement in bed transferring: This measure replaces the previously reported measure improvement in transferring. It provides a more focused measurement of the ability to turn and position oneself in bed and transfer to and from the bed.
- Emergency Department Use without Hospitalization: This measure replaces the previously reported measure: Emergent care. It excludes emergency department visits that result in a hospital admission because those visits are already captured in the acute care hospitalization measure.

To summarize, the following outcome measures, which comprise measurement of HH care quality, will be publicly reported beginning in July 2011:

- Improvement in ambulation/locomotion;
- Improvement in bathing;
- Improvement in bed transferring;
- Improvement in management of oral medications;
- Improvement in pain interfering with activity;
- Acute care hospitalization;
- Emergency Department Use without Hospitalization;
- Improvement in dyspnea;
- Improvement in status of surgical wounds; and
- Increase in number of pressure ulcers.

We implemented use of the OASIS–C (Form Number CMS–R–245 (OMB# 0938–0760)) on January 1, 2010. This revision to OASIS was tested and has been distributed for public comment and other technical expert recommendations over the past few years. The OASIS–C is on the CMS Web site at *http://www.cms.hhs.gov/HomeHealthQualityInits/12_HHQIOASISDataSet.asp#TopOfPage.*

As a result of changes to the OASIS data set, process of care measures are available as additional measures of HH quality. We published information about new process measures in the August 13, 2009 proposed rule (74 FR 40960) and in the November 10, 2009 final rule with comment period (74 FR 58096). We proposed and made final the decision to update the Home Health Compare Web site in October 2010 to reflect the addition of the following 13 new *process* measures:

- Timely initiation of care;
- Influenza immunization received for current flu season;
- Pneumococcal polysaccharide vaccine ever received;
- Heart failure symptoms addressed during short-term episodes;

- Diabetic foot care and patient education implemented during short-term episodes of care;
- Pain assessment conducted;
- Pain interventions implemented during short-term episodes;
- Depression assessment conducted;
- Drug education on all medications provided to patient/caregiver during short-term episodes;
- Falls risk assessment for patients 65 and older;
- Pressure ulcer prevention plans implemented;
- Pressure ulcer risk assessment conducted; and
- Pressure ulcer prevention included in the plan of care.

The implementation of OASIS–C impacts the schedule of quality measure reporting for CY 2010 and CY 2011. While sufficient OASIS–C data are collected and risk models are developed, the outcome reports (found on the Home Health Compare Web site and the contractor outcome reports used for HHA's performance improvement activities) will remain static with OASIS–B1 data. The last available OASIS–B1 reports will remain in the system and on the HHC site until they are replaced with OASIS–C reports. Sufficient numbers of patient episodes are needed in order to report measures based on new OASIS–C data. This is important because measures based on patient sample sizes taken over short periods can be inaccurate and misleading due to issues like seasonal variation and under-representation of long-stay HH patients. Once sufficient OASIS–C data have been collected and submitted to the national repository, we will begin producing new reports based on OASIS–C.

December 2009 was the last month for which OBQI/M data was calculated for OASIS–B1 data and OASIS–B1 OBQI/M reports continue to be available after March 2010. OASIS–C process measures are available to preview as of September 2010 and will be publicly reported in October 2010. OASIS–C outcome measures will be available to preview in May 2011 and will be publicly reported in July 2011.

The following is a summary of the comments we received regarding the Home Health Care Quality Improvement: OASIS proposal.

Comment: One commenter expressed support for the proposed changes in OASIS reporting. Another commenter stated support for quality reporting. Commenters also stated they support the changes in OASIS publicly reported indicators and expressed support for the continued submission of OASIS data and expressed their commitment to continue working with CMS to develop appropriate measures. Commenters also support the adoption of OASIS–C process measures and applaud CMS for creating this patient-focused system.

Response: We appreciate the positive feedback regarding changes in the measures which will be publicly reported and the quality reporting efforts in general. We appreciate the industry's encouragement and willingness to adopt the new methods that reflect the quality of care provided to Medicare beneficiaries.

Comment: One commenter expressed concern with the addition of the Increase in Number of Pressure Ulcers measure to publicly reported outcomes. The commenter stated that it is not an appropriate measure of the homecare agencies' effectiveness of care but rather of the family's effectiveness and that HHAs are not responsible for the care provided 24 hours a day.

Response: Though HH services are provided on an intermittent, part-time basis, and HHA staff are not present in the home 24 hours per day, the HHA is responsible for determining that the level of care provided by the agency is safe and adequate to manage the needs of the patient. Monitoring and addressing adherence to the Plan of Care established by the physician, HHA, patient, and family is the responsibility of the HHA. In many cases, though we agree not all, the provision of skilled nursing services, which includes family/caregiver instruction, in conjunction with the provision of personal care services, can accomplish a great deal in the prevention of new pressure ulcers. We believe this is an important indicator of HHA performance related to best practices, patient safety, and comfort. This measure is also harmonized with similar measures in other settings. We will move forward with reporting Increase in Number of Pressure Ulcers on Home Health Compare in July 2011.

Comment: One commenter urged CMS to maintain "Improvement in Urinary Incontinence" among the publicly reported outcome measures, stating that this measure is of utmost importance to Medicare beneficiaries' quality of life and Medicare costs. Another commenter expressed disappointment in the removal of the outcome measure "Discharge to Community" from public reporting, stating their belief that this measure is one of the best measures of the effectiveness of HHA intervention.

Response: The Improvement in Urinary Incontinence outcome measure did not receive endorsement from NQF when reviewed in March 2009. NQF's rationale primarily involved concerns about reliability of the data, that is, that this information is difficult to capture reliably due to issues with patient reporting. We have also received feedback from providers and consumers, which leads us to believe that the measure lacks salience and meaningful use, particularly among consumers. It appears that consumers are unable to link this outcome to the HHA's performance and cannot attribute improvement to HHA care.

The Discharge to Community measure also did not receive endorsement from NQF when reviewed in March 2009. NQF determined that this measure did not reflect whether patients met their treatment goals, but only that they were discharged from services, which may have been for other reasons unrelated to the care provided. NQF also noted that the acute care hospitalization measure captures many of these patients. However, the comments offered do present meaningful information that we will find useful when considering resubmitting these measures for NQF endorsement. Please note that these measures will continue to be provided to agencies for use in quality/performance improvement efforts.

Comment: One commenter recommended CMS consider ending the requirement that OASIS data be submitted for Medicare Advantage (MA) plans, noting that that they have not found an MA plan that has used the data in the past decade.

Response: Under section 1891(b) of the Act, the Secretary is responsible for assuring that the Conditions of Participation (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 Medicare funds. Medicare funds are used to pay for care provided to patients covered by MA plans.

Under sections 1861(o), 1871, and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth at 42 CFR Part 484, Conditions of Participation: Home Health Agencies. The current HH CoPs require that all HHAs participating in Medicare and Medicaid (including managed care organizations providing HH services to Medicare and Medicaid beneficiaries) collect and report OASIS data on adult, non-maternity patients receiving skilled care.

One of the major purposes of collecting and reporting OASIS data is to track the quality of patient outcomes.

It is important that the content of reports depicting the status of patient outcomes and the HHA use of best practices include measures related to *all* Medicare beneficiaries, including those covered by MA Plans. It is also important to include MA beneficiary data in the calculation of agency, state, and national averages in both agency level and public quality measure reports. This quality information is available for use and is actually used not only by payers, but also by researchers, providers, and consumers of HH services. We are not currently considering a change in the OASIS reporting requirements.

Comment: Two commenters urge that CMS remove New York State's LTHHCP agencies from the *Pay for Reporting* (P4R) initiative in order to ensure that these programs will not be adversely/unfairly affected or penalized once CMS implements a *Pay for Performance* system. The commenter also requests that any special needs CHHAs be removed from the P4R initiative for the same reasons.

Response: The *Pay for Reporting* initiative requires that all Medicare certified HHAs submit OASIS assessments. The HH P4R requirements are based in section 5201(c)(2) of the DRA, which provides for an adjustment to the HH market basket percentage update depending on their submission of quality data. HHAs that submit the required quality data using OASIS will receive payments based on the full HH market basket update each calendar year. If a HHA does not submit quality data, the HH market basket will be reduced by 2 percentage points based on annual payment rule and the Congress. The submission of OASIS assessments is also required by the CoPs and as a Condition of Payment. The only exceptions to the reporting requirements are:

- Prepartum and postpartum patients;
- Patients under the age of 18;
- Patients not receiving skilled health care services; and
- Non-Medicare/non-Medicaid patients (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement).

Since New York's LTHHCP agencies or any special needs CHHAs do not fall within these exclusions, we are not waiving their reporting requirements.

The Affordable Care Act requires that we submit a Report to Congress outlining a Value Based Purchasing Plan for HHAs by October, 1, 2011. We are in the process of developing the Home Health Value Based Purchasing report and decisions have not yet been made about this issue. Therefore, it would be premature to link a Pay for Performance system to OASIS submission at this time.

Comment: One commenter expressed concern that it is too soon to publicly report the new OASIS–C process measures and request an additional year of study and refinement before these measures are released to the public. The commenter also states that most agencies have no way to identify where they stand with regard to the process items and that many of these items remain problematic and confusing to providers.

Response: The process measure reports, which detail the 47 new process measures based on OASIS–C, were made available to HHAs via the CASPER reporting system as of September 1, 2010. The availability of these reports meets the statutory requirement that HHAs have opportunity to view their measures prior to public reporting. Thirteen of the process measures were posted on Home Health Compare in October 2010.

We recognize that agencies have experienced many changes with the transition to OASIS–C on January 1, 2010 and will need to continue to make adjustments to move their newly measured performance forward. These changes and adjustments are all intended to improve the care provided to beneficiaries and to provide best practices that HHAs may choose to implement for their HH patients. Process measures are mechanisms for assessing the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in the optimal time period. Through efforts over time, HHAs should see improvements in their process measure reports, including those that are publicly reported. Recognizing that the first set of reports will provide the baseline of performance on which HHAs can build, we will continue with the proposed reporting plan and timeline.

There are several resources available to assist with any remaining confusion within the HH industry related to the process items that include the following:

- In 2009, CMS provided three Train the Trainer calls via the Medicare Learning Network one of which focused on process items and measures. All three transcripts are still available at *http://www.cms.gov/HomeHealthQualityInits/03_EducationalResources.asp#TopOfPage.*
- A new training video specific to Process-Based Quality Improvement (PBQI) is now available on YouTube at *http://www.youtube.com/watch?v=hNno1GIVAPA.*
- Four new and/or revised manuals are also available as downloads from the Home Health Quality Initiatives site at *http://www.cms.gov/HomeHealthQualityInits/.*
- For questions regarding the OASIS items, the OASIS Answers mailbox can be accessed at *cmsoasisquestions@oasisanswers.com.*

Comment: One commenter expressed concern with the increased demands placed upon HHAs to provide information regarding the quality of their services, and that possibly these newer requirements are unfair to HHAs that are honestly trying to provide good services and that agencies would stop admitting patients that are in dire need of HH services because outcomes would not be good. The commenter was concerned at the presence of unscrupulous HHAs that are taking advantage of seniors who are deserving of quality HH care, and advised CMS to be more cautious as to whom they let into the program. Another commenter stated that OASIS is very time consuming and the addition of HHCAHPs is "enough." Some commenters suggested that OASIS–C, HHCAHPS, and general Quality Management requirements are unfunded mandates; that are very costly to implement. One commenter expressed concern that there is no mention of risk adjustments on publicly reported data. Another commenter noted that neither quality measures nor HHCAHPS address communication or swallowing capabilities.

Response: We appreciate these commenters' concerns about fraudulent HH providers. We are also aware that newer requirements, such as OASIS–C and HHCAHPS, may be perceived as an additional and burdensome responsibility that HHAs now have. However, we believe that both the OASIS–C process measures and HHCAHPS will be very useful to both HH beneficiaries and HHAs. Recipients of HH services will have access to more information about the quality of HH care. HHAs can utilize the data gleaned from these new requirements for their internal quality improvement purposes, which will assist them as businesses and providers. The HH quality requirements are intended to provide improved support for agency quality improvement efforts and enhanced quality information for both providers and beneficiaries. Process of care items that measure agencies' use of evidence-based practices that have been shown to prevent exacerbation of serious conditions can improve care received by

individual patients and can provide guidance to agencies on how to improve care and avoid adverse events.

Regarding the addition of process measures and best practices, it is also important to note that HHAs are encouraged to use these best care practices but *they are not mandated* under the current CoPs.

With the exception of requiring that the item be included on the assessment form and answered, we are not prescribing the content of agency clinical assessments or mandating specific processes of care. There is no requirement for agencies to change their care processes to match the evidence-based practices measured in the OASIS C. It is up to each agency to determine which practices it will implement based on its own patients and operations. Regarding risk adjustment, all outcome measures will be risk adjusted for HHA reports and for public reporting. Regarding the absence of measures related to communication and swallowing, the development of both quality measures and patient satisfaction questions are dynamic processes and we will consider these categories in our future efforts.

After considering the comments submitted, we have decided to finalize what was originally proposed.

b. Home Health Care CAHPS Survey (HHCAHPS)

In the HH PPS Rate Update for CY 2010 final rule (74 FR 58078), we expanded the HH quality measures reporting requirements for Medicare-certified agencies to include the CAHPS® Home Health Care (HHCAHPS) Survey for the CY 2012 annual payment update (APU). We are maintaining our existing policy as promulgated in the HH PPS Rate Update for CY 2010, and are moving forward with its plans for HHCAHPS linkage to the P4R requirements affecting the HH PPS rate update for CY 2012.

As part of the U.S. Department of Health and Human Services' (DHHS) Transparency Initiative, we have implemented a process to measure and publicly report patient experiences with HH care using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program. The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The HHCAHPS survey presents HH patients with a set of standardized questions about their HH care providers and about the quality of their HH care. Prior to this survey, there was no national standard for collecting information about patient experiences that would enable valid comparisons across all HHAs.

(i) Background and Description of the HHCAHPS

AHRQ, in collaboration with its CAHPS grantees, developed the CAHPS® Home Health Care Survey with the assistance of many entities (for example, government agencies, professional stakeholders, consumer groups and other key individuals and organizations involved in HH care). The HHCAHPS survey was designed to measure and assess the experiences of those persons receiving HH care with the following three goals in mind:

- To produce comparable data on patients' perspectives of care that allow objective and meaningful comparisons between HHAs on domains that are important to consumers;
- To create incentives for agencies to improve their quality of care through public reporting of survey results; and
- To hold health care providers accountable by informing the public about the providers' quality of care.

The development process for the survey began in 2006 and included a public call for measures, review of the existing literature, consumer input, stakeholder input, public response to **Federal Register** notices, and a field test conducted by AHRQ. AHRQ conducted this field test to validate the length and content of the CAHPS® Home Health Care Survey. We submitted the survey to the NQF for consideration and endorsement via their consensus process. NQF endorsement represents the consensus opinion of many healthcare providers, consumer groups, professional organizations, health care purchasers, Federal agencies, and research and quality organizations. The survey received NQF endorsement on March 31, 2009. The HHCAHPS survey received clearance from OMB on July 18, 2009, and the OMB number is 0938–1066.

The HHCAHPS survey includes 34 questions covering topics such as specific types of care provided by HH providers, communication with providers, interactions with the HHA, and global ratings of the agency. For public reporting purposes, we will utilize composite measures and global ratings of care. Each composite measure consists of four or more questions regarding one of the following related topics:

- Patient care
- Communications between providers and patients
- Specific care issues (medications, home safety, and pain)

There are also two global ratings; the first rating asks the patient to assess the care given by the HHA's care providers; and the second asks the patient about his or her willingness to recommend the HHA to family and friends.

The survey is currently available in five languages. At the time of the CY 2010 HH PPS final rule published on November 10, 2009, HHCAHPS was only available in English and Spanish translations. In the proposed rule for CY 2010, we stated that CMS would provide additional translations of the survey over time in response to suggestions for any additional language translations. We now offer HHCAHPS in English, Spanish, Chinese, Russian, and Vietnamese languages. We will continue to consider additional translations of the HHCAHPS in response to the needs of the HH patient population.

The following types of HH care patients are eligible to participate in the HHCAHPS survey:

- Current or discharged Medicare and/or Medicaid patients who had at least one skilled HH visit at any time during the sample month;
- Patients who were at least 18 years of age at any time during the sample period, and are believed to be alive;
- Patients who received at least two skilled care visits from HHA personnel during a 2-month look-back period. (Note that the 2-month look-back period is defined as the 2-month period prior to and including the last day in the sample month);
- Patients who have not been selected for the monthly sample during any month in the current quarter or during the 5 months immediately prior to the sample month;
- Patients who are not currently receiving hospice care;
- Patients who do not have "maternity" as the primary reason for receiving HH care; and
- Patients who have not requested "no publicity status."

We are maintaining for the CY 2012 APU the existing requirements for Medicare-certified agencies to contract with an approved HHCAHPS survey vendor. Beginning in summer 2009, interested vendors applied to become approved HHCAHPS survey vendors. The application process is online at *https://www.homehealthcahps.org*. Vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We now have 40 approved HHCAHPS survey vendors. In this rule, we also

codify the requirements for being an approved HHCAHPS survey vendor for the CY 2013 APU.

HHAs started to participate in HHCAHPS on a voluntary basis beginning in October 2009. We define "voluntary participation" as meaning that HHCAHPS participation is not attached to the quality reporting requirement for the APU. These agencies selected a vendor from the list of HHCAHPS approved survey vendors, which is available at *https://www.homehealthcahps.org*.

(ii) Public Display of the Home Health Care CAHPS Survey Data

The Home Health Care CAHPS data will be incorporated into the Home Health Compare Web site to complement the clinical measures. The HHCAHPS data displays will be very similar to those of the Hospital CAHPS (HCAHPS) data displays and presentations on the Hospital Compare Web site, where the patients' perspectives of care data from HCAHPS are displayed along with the hospital clinical measures of quality. We believe that the HHCAHPS will enhance the information included in Home Health Compare by providing Medicare beneficiaries a greater ability to compare the quality of HHAs. We anticipate that the first reporting of HHCAHPS data will be in spring/summer 2011. The first reporting of HHCAHPS data will include data that were collected in the voluntary period of HHCAHPS data collection (October 2009 through September 2010), prior to the period when HHCAHPS data collection will count toward the 2012 APU requirements. HHAs will be able to suppress the public reporting of data collected in the voluntary period of data collection.

(iii) Participation Requirements for CY 2012: The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey

In the CY 2010 HH PPS final rule (74 FR 58078, *et seq.*), we stated that HHCAHPS would not be required for the APU for CY 2011. However, we stated that data collection should take place beginning in CY 2010 in order to meet the HHCAHPS reporting requirements for the CY 2012 APU Medicare-certified agencies were asked to participate in a dry run for at least 1 month in third quarter of 2010, and begin continuous monthly data collection in October 2010 in accordance with the Protocols and Guidelines Manual located on the HHCAHPS Web site at *https://www.homehealthcahps.org.*

The dry run data should be submitted to the Home Health CAHPS® Data Center by 11:59 p.m., Eastern Standard Time on January 21, 2011. The dry run data will not be publicly reported on the CMS Home Health Compare Web site. The purpose of the dry run is to provide an opportunity for vendors and HHAs to acquire first-hand experience with data collection, including sampling and data submission to the Home Health CAHPS® Data Center.

The mandatory period of data collection for the CY 2012 APU includes the dry run data in the third quarter 2010, data from the fourth quarter 2010 (October, November and December 2010), and data from the first quarter 2011 (January, February and March 2011). We previously stated that all Medicare-certified HHAs should continuously collect HHCAHPS survey data for every month in every quarter beginning with the fourth quarter (October, November, and December) of 2010, and submit these data for the fourth quarter of 2010 to the Home Health CAHPS® Data Center by 11:59 p.m., Eastern Daylight Time on April 21, 2011. The data from the 3 months of the first quarter 2011 should be submitted to the Home Health CAHPS® Data Center by 11:59 p.m., Eastern Daylight Time on July 21, 2011. These data submission deadlines are firm (that is, no late submissions will be accepted).

These periods (a dry run in third quarter 2010, and 6 months of data from October 2010 through March 2011) have been deliberately chosen to comprise the HHCAHPS reporting requirements for the CY 2012 APU because they coincide with the OASIS–C reporting requirements that are due by June 30, 2011 for the CY 2012 APU. In the previous rule, we stated that the HHCAHPS survey data would be submitted and analyzed quarterly, and that the sample selection and data collection would occur on a monthly basis. HHAs should target 300 completed HHCAHPS survey annually. Smaller agencies that are unable to reach 300 survey completes by sampling would survey all HHCAHPS eligible patients.

We stated that survey vendors initiate the survey for each monthly sample within 3 weeks after the end of the sample month. We wrote that all data collection for each monthly sample would have to be completed within 6 weeks (42 calendar days) after data collection began. Three survey administration modes could be used: mail only; telephone only; and mail with telephone follow-up (the "mixed mode"). We also conveyed that for mail-only and mixed-mode surveys, data collection for a monthly sample would have to end 6 weeks after the first questionnaire was mailed. We stated that for telephone-only surveys, data collection would have to end 6 weeks following the first telephone attempt. These criteria would remain the same for HHCAHPS data collection to meet the CY 2012 APU requirements.

As stated in the CY 2010 HH PPS final rule (74 FR 58078), we would exempt Medicare-certified HHAs certified on or after April 1, 2011 from the HHCAHPS reporting requirements for CY 2012 as data submission and analysis will not be possible for an agency this late in the reporting period for the CY 2012 APU requirements.

We would also exempt Medicare-certified agencies from the HHCAHPS reporting requirements if they have fewer than 60 HHCAHPS eligible unique patients from April 1, 2009 through March 31, 2010. In the CY 2010 HH PPS final rule, we stated that by June 16, 2010, HHAs would need to provide CMS with patient counts for the period of April 1, 2009 through March 31, 2010. We have posted a form that the HHAs need to use to submit their patient counts on the Web site at *https://www.homehealthcahps.org.* This patient counts reporting requirement pertains only to Medicare-certified HHAs with fewer than 60 HHCAHPS eligible, unduplicated or unique patients for that time period. The aforementioned agencies would be exempt from conducting the HHCAHPS survey for the APU in CY 2012. In this rule, we codify the requirement that if an HHA has fewer than 60 eligible unique HHCAHPS patients annually, then they must submit to CMS their total patient counts in order to be exempt from the HHCAHPS reporting requirement.

For CY 2012, we maintain our policy that all HHAs, unless covered by specific exclusions, meet the quality reporting requirements or be subject to a 2 percentage point reduction in the HH market basket percentage increase in accordance with section 1895(b)(3)(B)(v)(I) of the Act.

A reconsiderations and appeals process is being developed for HHAs that fail to meet the HHCAHPS data collection requirements. We proposed that these procedures will be detailed in the CY 2012 HH payment rule, the period for which HHCAHPS data collection would be required for the HH market basket percentage increase. During September through October 2011, we will compile a list of HHAs that are not compliant with OASIS–C and/or HHCAHPS for the 2012 APU requirements. These HHAs would

receive explicit instructions about how to prepare a request for reconsideration of the CMS decision, and these HHAs would have 30 days to file their requests for reconsiderations to CMS. By December 31, 2011, we would provide our final determination for the quality data requirements for CY 2012 payment rates. HHAs have a right to appeal to the Prospective Reimbursement Review Board (PRRB) if they are not satisfied with the CMS determination.

(iv) Oversight Activities for the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey

We stated that vendors and HHAs would be required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that HHAs and approved survey vendors follow the Protocols and Guidelines Manual. As stated, all approved survey vendors must develop a Quality Assurance Plan (QAP) for survey administration in accordance with the Protocols and Guidelines Manual. The QAP should include the following:

- An organizational chart;
- A work plan for survey implementation;
- A description of survey procedures and quality controls;
- Quality assurance oversight of on-site work and of all subcontractors work; and
- Confidentiality/Privacy and Security procedures in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted on August 21, 1996).

As part of the oversight activities, the HHCAHPS Survey Coordination Team would conduct on-site visits and/or conference calls. The HHCAHPS Survey Coordination Team would review the survey vendor's survey systems, and would assess administration protocols based on the Protocols and Guidelines Manual posted at *https://www.homehealthcahps.org.* We stated that all materials relevant to survey administration would be subject to review. The systems and program review would include, but not be limited to the following

- Survey management and data systems;
- Printing and mailing materials and facilities;
- Data receipt, entry and storage facilities; and
- Written documentation of survey processes. Organizations would be given a defined time period in which to correct any problems and provide follow-up documentation of corrections for review. Survey vendors would be subject to follow-up site visits as needed.

(v) HHCAHPS Requirements for CY 2013

For the CY 2013 APU, we will begin to require that four quarters of data for HHCAHPS be collected and reported. The data collection period would include second quarter 2011 through first quarter 2012. HHAs will be required to submit to the Home Health CAHPS Data Center data for the second quarter 2011 by 11:59 p.m., Eastern Daylight Time on October 21, 2011; for the third quarter 2011 by 11:59 p.m., Eastern Standard Time on January 21, 2012; for the fourth quarter 2011 by 11:59 p.m., Eastern Daylight Time on April 21, 2012; and for the first quarter 2012 by 11:59 p.m., Eastern Daylight Time on July 21, 2012.

As noted, we exempt HHAs receiving Medicare certification on or after April 1, 2012 from the full HHCAHPS reporting requirement for the CY 2013 APU, as data submission and analysis will not be possible for an agency that late in the reporting period for the CY 2013 APU requirements. However, we require that new HHAs that receive Medicare certification during CY 2012 begin HHCAHPS data collection and submission the quarter following receipt of the CMS Certification Number (CCN) in order to receive the CY 2013 APU.

As noted, we require that all HHAs that have fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2010 through March 31, 2011 will be exempt from the HHCAHPS data collection and submission requirements for the CY 2013 APU. For the CY 2013 APU, agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients would be required to submit their counts on the form posted on *https://www.homehealthcahps.org*, the Web site of Home Health Care CAHPS by 11:59 p.m., e.s.t. on January 21, 2012. This deadline is firm, as are all of the quarterly data submission deadlines.

We proposed to codify the HHCAHPS survey vendor requirements to be effective with the CY 2013 APU. In our regulation, we are stating in § 484.250(c)(2) that applicants to become approved HHCAHPS survey vendors must have been in business for a minimum of 3 years and have conducted "surveys of individuals" for at least 2 years immediately preceding the application to become a survey vendor for HHCAHPS. For purposes of the approval process for HHCAHPS survey vendors, a "survey of individuals" is defined as the collection of data from individuals selected by statistical sampling methods and the data collected are used for statistical purposes. An applicant organization must:

- Have conducted surveys of individuals responding about their own experiences, not of individuals responding on behalf of a business or organizations (establishment or institution surveys);
- Be able to demonstrate that a statistical sampling process (that is, simple random sampling [SRS], proportionate stratified random sampling [PSRS], or disproportionate stratified random sampling [DSRS]) was used in the conduct of previously or currently conducted survey(s);
- Be able to demonstrate that it, as an organization, has conducted surveys for at least two years, in which statistical samples of individuals were selected. If staff within the applicant organization has relevant experience obtained while in the employment of a different organization, that experience may not be counted toward the 2-year minimum of survey experience; and
- Currently possess all required facilities and systems to implement the HHCAHPS Survey.

We also proposed that the following examples of data collection activities would not satisfy the requirement of valid survey experience for approved vendors as defined for the HHCAHPS, and these would not be considered as part of the experience required of an approved vendor for HHCAHPS:

- Polling questions administered to trainees or participants of training sessions or educational courses, seminars, or workshops;
- Focus groups, cognitive interviews, or any other qualitative data collection activities;
- Surveys of fewer than 600 individuals;
- Surveys conducted that did not involve using statistical sampling methods;
- Internet or Web-based surveys; and
- Interactive Voice Recognition Surveys.

We also proposed to codify the criteria that would make organizations ineligible to become HHCAHPS approved survey vendors. We proposed to require that any organization that owns, operates, or provides staffing for a HHA not be permitted to administer its own HHCAHPS Survey or administer the survey on behalf of any other HHA. We began the HHCAHPS with the belief, based on input from many stakeholders

and the public, that an independent third party (such as a survey vendor) will be best able to solicit unbiased responses to the HHCAHPS Survey. Since HH patients receive care in their homes, this survey population is particularly vulnerable and dependent upon their HHA caregivers. Therefore, in § 484.250(c), we proposed to require that HHAs contract only with an independent, approved HHCAHPS vendor to administer the HHCAHPS survey on their behalf. Furthermore, in § 484.250(c)(2), we stated that "No organization, firm, of business that owns, operates, or provides staffing for an HHA is permitted to administer its own Home Health Care CAHPS (HHCAHPS) Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations will not be approved by CMS as HHCAHPS survey vendors."

Specifically, we proposed that the following types of organizations would not be eligible to administer the HHCAHPS Survey as an approved HHCAHPS vendor:

- Organizations or divisions within organizations that own or operate a HHA or provide HH services, even if the division is run as a separate entity to the HHA;
- Organizations that provide telehealth, telemonitoring of HH patients, or teleprompting services for HHAs; and
- Organizations that provide staffing, whether personal care aides or skilled services staff, to HHAs for providing care to HH patients.

(vi) For Further Information on the HHCAHPS Survey

We encourage HHAs interested in learning about the survey to view the HHCAHPS Survey Web site at *https://www.homehealthcahps.org.* Agencies can also call toll-free (1–866–354–0985), or send an email to the HHCAHPS Survey Coordination Team at *HHCAHPS@rti.org* for more information.

The following is summary of the comments we received regarding the HHCAHPS proposal.

Comment: We received comments that the response rate on HHCAHPS (about 30 percent) will be low and thus difficult to meet the minimum survey requirement.

Response: We conducted a Survey Mode Experiment for the HHCAHPS with 75 HHAs nationwide with data collection conducted between September 21, 2009, and January 5, 2010. The overall response rate (for all three modes of mail only, telephone only and mixed mode of mail with telephone follow-up) was 45.7 percent. As long as the HHCAHPS survey protocols are followed and that the random sampling is completed correctly, the response rate of the HHCAHPS is not of great concern. We have not designated a minimum survey response rate requirement for the HHAs.

Comment: Some commenters believe that the costs to HHAs to implement the HHCAHPS, including administrative and vendor costs, will be very high (estimates range from $3,500 for 300 to 500 surveys, up to $85,000).

Response: The commenters supplied a figure of $3,500 for 300 to 500 surveys, but did not provide the number of surveys conducted for the $85,000 figure. Our Web site research shows that most of the vendors are charging between approximately $2,500 and $5,000 for about 300 survey completes. We recognize that vendors will charge different amounts for the survey, and highly recommend that HHAs "shop around" for the best value for their agency. The HHCAHPS target for the number of survey completes is 300 regardless of agency size, thus the $85,000 is not a realistic figure for the cost of conducting HHCAHPS. The approved HHCAHPS survey vendor list is available on *https://www.homehealthcahps.org.* Currently, 40 vendors are approved to conduct the HHCAHPS survey and additional vendors will be approved in the coming months.

Comment: Some commenters stated that the requirement for HHCAHPS should begin in CY 2013 and not in CY 2012.

Response: We are not delaying the HHCAHPS requirement for the APU to CY 2013, as our data suggest that HHAs began preparation for the HHCAHPS requirement since its pendency has been announced and discussed in prior regulations. HHAs anticipated the HHCAHPS requirement and this has allowed the HHAs to prepare for the HHCAHPS requirement. Our data, as of mid-October 2010 show that nearly 8,000 Medicare-certified HHAs have either applied for an exemption from participation in HHCAHPS or registered for credentialing to begin HHCAHPS. However, we will not have a certain estimate of the HHA participation rate in the HHCAHPS dry run until after the deadline for that data, which is 11:59 p.m., e.s.t. on January 21, 2011.

In the CY 2010 HH PPS final rule (78 FR 58078), we delayed the HHCAHPS requirement for the APU, from CY 2011 to CY 2012. We announced in that final rule (78 FR 58078) that HHAs would need to conduct a dry run in third quarter 2010 and continuously collect survey data beginning in the fourth quarter 2010 and moving forward.

Although we carefully considered the comments that we received requesting that HHCAHPS linkage to the APU be delayed until 2013, we believe that HHAs have had sufficient notice of the HHCAHPS requirements and that we do not need to delay the linkage of HHCAHPS to the CY 2013 APU. We initially discussed the HHCAHPS Survey in the May 4, 2007 proposed rule (72 FR 25356) and in the November 3, 2008 Notice (73 FR 65357). In the CY 2010 HH PPS proposed rule (74 FR 40948), we proposed to expand the HH quality measures reporting requirements to include the CAHPS Home Health Care (HHCAHPS) Survey for the CY 2011 APU. In the CY 2010 HH PPS final rule (74 FR 58078), we stated that the HHCAHPS would be effective with the CY 2012 APU, instead of with the CY 2011 APU.

Comment: Some commenters questioned the threshold of 300 surveys which would be too difficult for small HHAs to achieve, and too little for big HHAs. The commenters stated that they would not be able to make statistically valid comparisons between small and large HHAs with the same sample size of 300 completed surveys per HHA.

Response: We understand concerns about the sample size. However, an established principle in statistics is that a sample size in absolute numbers is more important than a proportion of the population surveyed. Surveying a sample of 300 will produce the same level of precision whether the sample is 10 percent, 1 percent, or even 0.01 percent of the total population. The larger the sample (even if under 300), the less variability there will be in an agency's ratings over time. Therefore, in the final rule we are moving forward with the target sample size of 300 for HHCAHPS as proposed.

We appreciate this question clarifying whether agencies must submit 300 completed surveys on an annual basis. In the proposed rule and in this final rule, we emphasized that HHAs should target 300 completes annually which averages about 25 completes a month. We understand that 300 may be difficult for some small agencies to achieve. Therefore, smaller agencies that are unable to reach 300 survey completes by sampling should survey all HHCAHPS eligible patients. We will accept less than 300 surveys completed annually if an agency is unable to achieve that number. Compliance is based on whether the agency did the survey, following the instructed protocols and not based on the number of patients that responded to the survey.

Comment: We received comments that the HHCAHPS survey is too long.

Response: The version of the HHCAHPS survey that was used in the Agency for Healthcare Research and Quality (AHRQ) field test in 2008 had 58 items, and the length of that survey did not appear to influence the completion of the survey. However, as a result of intensive data analysis and input from the stakeholders and the Technical Expert Panel, over 20 questionnaire items were eliminated from the field test survey. The current 34-item questionnaire (which received National Quality Forum endorsement) was the outcome of this development process. We believe that the length of the survey represents an effective compromise and achieves the goal of providing key quality measures of the patient perspectives of care while at the same time keeping the survey as short as possible. We are not shortening the survey in this final rule.

Comment: Some commenters believe that the HHCAHPS survey questions are too confusing. Other commenters stated that the HHCAHPS survey is poorly crafted.

Response: The developmental work on the Home Health Care CAHPS began in mid-2006, and the first survey was field-tested (to validate the length and content of the survey) in 2008 by the AHRQ and the CAHPS grantees, and the final survey was used in a national, randomized mode experiment in 2009–2010. A rigorous, scientific process was used in the development of the survey, including: A public call for measures; literature reviews; focus groups with HH patients; cognitive interviews (several rounds in 2007) with HH patients; extensive stakeholder input; technical expert panel reviews, comprehensive assessment review and subsequent endorsement in March 2009 by the National Quality Forum (which represents the consensus of many health care providers, consumer groups, professional associations, purchasers, federal agencies and research and quality organizations); and public responses to **Federal Register** notices.

We appreciate the commenters' sensitivity to the HH patients in asking about the usability of the HHCAHPS survey. The Flesch-Kincaid reading test showed that the HHCAHPS survey is at less than a seventh grade level. More importantly though, if patients are unable to answer the survey due to decreased capacities, a family or friend who is not associated with the HH services given to the patient, may assist the patient and answer the questions on behalf of the selected HH patient in the HHCAHPS HHA sample.

Comment: We received comments that the HHAs need more education and information about HHCAHPS before it is a requirement.

Response: We initially discussed the HHCAHPS Survey in the May 4, 2007 proposed rule (72 FR 25356, 25423) and in the November 3, 2008 Notice (73 FR 65357, 65358). In the CY 2010 HH PPS proposed rule (August 13, 2009), we proposed to expand the HH quality measures reporting requirements to include the CAHPS Home Health Care (HHCAHPS) Survey. In the CY 2010 HH PPS final rule, we stated that the HHCAHPS would be effective with the CY 2012 APU. The HHCAHPS requirements for CY 2012 have been discussed on the CMS Home Health and Hospice Open Door Forums from late 2009 to the present. We have posted information regarding the HHCAHPS requirements for CY 2012 on all CMS sponsored Web sites for Medicare and State Medicaid issues. We have spoken on this topic of HHCAHPS requirements for CY 2012 at conferences with the National Association for Home Care and on conference calls with the Visiting Nurse Associations of America. We have spoken about the HHCAHPS requirements for CY 2012 on the CMS State Medicaid sponsored calls. We have maintained a very thorough and up-to-date Web site at *https://www.homehealthcahps.org* that emphasized the importance of starting HHCAHPS in order to meet the requirements for CY 2012.

Comment: We received comments that HHCAHPS does not address communication and swallowing issues for HH care patients.

Response: We appreciate this input from the commenter and note that none of the HHCAHPS questions concern such specific issues since the number of issues that could be addressed in a survey of this length is limited. The main goal of the HHCAHPS is to obtain the patients' perspectives of care regardless of the specific needs of the patients.

Comment: Some commenters question how they will know that the approved survey vendors are truly independent of HHAs and telehealth companies and ask what would happen if they inadvertently utilized an approved HHCAHPS vendor carrying on a prohibited financial relationship with another HHA.

Response: In this final rule, beginning with the CY 2013 APU, we will be requiring that all HHCAHPS approved survey vendors affirm at their oversight review, that they do not provide direct HH care services to the patients of the HHAs to which they are or will be contracting to conduct HHCAHPS on behalf of these HHAs. If an approved HHCAHPS survey vendor has been discovered to have falsified its affirmation, then that vendor will be immediately removed from the approved HHCAHPS survey vendor list. For those HHAs contracting with a vendor that is removed from the approved HHCAHPS vendor list, CMS will allow affected HHAs to transfer their submitted HHCAHPS data to another approved HHCAHPS vendor of their choice, and arrangements will be made should this occur in the middle of a quarterly period when vendor changes are not usually allowed for HHAs. Moreover, the HHCAHPS data from these affected HHAs will be reported on Home Health Compare; however, they will be designated with a footnote that explains the circumstance.

Comment: Some commenters stated that CMS should pay the HHAS for the (administrative) costs associated with HHCAHPS. We received a comment that it will cost $1.70 more per patient to obtain patient satisfaction input.

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

Comment: Some commenters believe that the HHCAHPS is not consistent with Hospital CAHPS (HCAHPS).

Response: We believe that the two surveys do not have to be consistent as the populations are different for Hospital and Home Health CAHPS. The differences in the types of questions reflect the differences in the nature of the services provided. However, both CAHPS surveys followed the same processes for the development of the survey and data collection protocols.

Comment: We received comments that about 70 percent of HHAs have not responded to the requirement for HHCAHPS thus far, since about July 2010, only 2,109 of the 10,500 HHAs have signed up, and another 1,114 have applied for exemptions from HHCAHPS. These figures show a poor rate of participation for HHCAHPS thus far.

Response: The HHAs' response to participating in HHCAHPS has changed since July 2010. Recent data show us that very nearly 8,000 of Medicare-certified HHAs have begun to engage in HHCAHPS, by either beginning the vendor approval process for the survey on *https://www.homehealthcahps.org,* or by applying for an exemption from the survey on *https://www.homehealthcahps.org.* We anticipate that this participation rate will increase, especially in the next few months. We are carefully watching the participation rate for HHCAHPS, and we will continue to inform the public about HHCAHPS through the Home Health and Hospice Open Door Forums, Web sites, and other means of communication.

Comment: One commenter stated concerns that while there are unscrupulous HHAS, most of the small HHAs have to comply with more requirements and face difficulty with remaining operational.

Response: We appreciate the commenter's concerns with the complex HHA system, which may allow unscrupulous providers to take advantage of senior citizens needing good HH services. We are aware that newer requirements, such as HHCAHPS, may be perceived as an additional cost and responsibility for HHAs. However, at the same time, we believe that HHCAHPS will benefit both seniors and other users of HH services because the survey will provide transparency and access to more information about the quality of HH care. In addition, HHAs will benefit with the information gleaned from HHCAHPS to utilize for their internal quality improvement purposes that benefit their agencies as businesses and providers of HH services.

Comment: We received a comment asking why interactive voice recognition (IVR) technology or internet-based technology would be excluded as a survey mode.

Response: We appreciate the commenter's knowledge about IVR technology and the possible inclusion of this technology as an additional survey mode for HHCAHPS. Through the period of developing and testing the HHCAHPS survey, the mail only, telephone only, and mail with telephone follow-up modes were found to be the most suitable for the patient population receiving HH care services. However, we are certainly open to continue testing additional survey modes for HHCAHPS, especially with the possibility of internet methodologies in the future.

Comment: We received a comment on how an approved survey vendor can simultaneously be an "independent" HHCAHPS surveyor and provide consultative services to the same HHAs on improving their operations. Such a situation is a classic conflict of interest.

Response: We appreciate this commenter's concerns about the independence that HH CAHPS vendors should maintain from the HHAs that are their clients. However, we believe that one of the goals of the HH care CAHPS survey is that HHAs can identify opportunities for improvement and ways to improve care. As long as the vendor does not directly provide care to patients, the vendor can independently provide guidance regarding methods to improve care provided by the HHA.

Comment: One commenter requested that we reevaluate and eliminate proposed criteria that would exclude potential vendors, as the criteria overstep CMS' authority to restrict legitimate business.

Response: We proposed these vendor requirements because we need to ensure that fully qualified organizations would be capable of undertaking the HHCAHPS surveys. Based on the vast input from stakeholders and the public, we proposed these requirements to ensure that an independent party will be best able to solicit unbiased, uncoerced responses to HHCAHPS survey.

Comment: One commenter stated that HHCAHPS is a proposed change that will be damaging to the HH industry and to the care and services provided to Medicare beneficiaries.

Response: We believe that HHCAHPS will benefit both seniors and other users of HH services because they will have access to more information about the quality of HH care. In addition, HHAs will benefit with the information gleaned from HHCAHPS to use for their internal quality improvement purposes and benefit their agencies as businesses and providers of HH services.

Comment: One commenter requested that CMS extend the deadline for agencies to apply for the HHCAHPS survey exemption beyond the original June 16, 2010 deadline.

Response: We will be extending the deadline for agencies to apply for HHCAHPS survey exemption for the CY 2012 APU to 11:59 p.m., e.s.t. on January 21, 2011. It is noted that the application for exemption from participation in HHCAHPS has to be submitted every year.

Comment: One commenter asked if CMS will require additional consent/authorizations to allow protected health information (PHI) patients to be included in HHCAHPS, since these PHI patients are now in the excluded categories for HHCAHPS. These additional consent/authorizations are required by New York State law.

Response: These PHI patients are ineligible to be included in HHCAHPS by New York State Law. We are prohibited by law to include PHI patients in the HHCAHPS survey under any circumstances. In the HHCAHPS Protocols and Guidelines manual which can be found at *https://homehealthcahps.org,* it states that patients who have a condition or illness for which the state in which the patient resides has regulations or laws restricting the release of patient information for patients with that condition (for example, patients with HIV/AIDS), that these patients are not eligible to be included in the HHCAHPS sampling procedures.

(vii) Provisions of the Final Rule

As a result of the comments, we will be extending the deadline for HHAs to apply for HHCAHPS survey exemption for the CY 2012 APU to 11:59 p.m., e.s.t. on January 21, 2011. Therefore, the deadline for the submission of the dry run data (collected in the third quarter of 2010) for the CY 2012 APU is January 21, 2011, and the deadline to apply for HHCAHPS survey exemption for the CY 2012 APU is also January 21, 2011. It is noted that the application for exemption from participation in HHCAHPS has to be submitted every year.

In this final rule, beginning with the CY 2013 APU, we will be requiring that all HHCAHPS approved survey vendors affirm at their oversight review, that they do not provide direct HH care services to the patients of the HHAs to which they are or will be contracting to conduct HHCAHPS on behalf of these HHAs. If an approved HHCAHPS survey vendor is found to have falsified its affirmation, then that vendor will be immediately removed from the approved HHCAHPS survey vendor list. For those HHAs contracting with an HHCAHPS vendor that is removed from the approved HHCAHPS vendor list, we will allow affected HHAs to transfer their submitted HHCAHPS data to another approved HHCAHPS vendor of their choice and arrangements will be made should this occur in the middle of a quarterly period when vendor changes are not usually allowed for HHAs. Moreover, the HHCAHPS data from these affected HHAs will be reported on Home Health Compare; however, they will be designated with a footnote that explains the circumstance.

There are no other changes noted from the CY 2011 HH PPS proposed rule.

3. Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence). Previously, we determined each HHA's labor market area based on definitions of Metropolitan Statistical Areas (MSAs) issued by the Office of Management and Budget (OMB). We have consistently used the pre-floor, pre-reclassified hospital wage index data to adjust the labor portion of the HH PPS rates. We believe the use of the pre-floor, pre-reclassified hospital wage index data results in an appropriate adjustment to the labor portion of the costs, as required by statute.

In the November 9, 2005 final rule for CY 2006 (70 FR 68132), we adopted revised labor market area definitions based on Core-Based Statistical Areas (CBSAs). At the time, we noted that these were the same labor market area definitions (based on OMB's new CBSA designations) implemented under the Hospital Inpatient Prospective Payment System (IPPS). In adopting the CBSA designations, we identified some geographic areas where there were no hospitals and, thus, no hospital wage data on which to base the calculation of the HH wage index. We continue to use the methodology discussed in the November 9, 2006 final rule for CY 2007 (71 FR 65884) to address the geographic areas that lack hospital wage data on which to base the calculation of their HH wage index. For rural areas that do not have IPPS hospitals, we use the average wage index from all contiguous CBSAs as a reasonable proxy. This methodology is used to calculate the wage index for rural Massachusetts. However, we could not apply this methodology to rural Puerto Rico due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005). For urban areas without IPPS hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. The only urban area without IPPS hospital wage data is Hinesville-Fort Stewart, Georgia (CBSA 25980).

On December 1, 2009, OMB issued Bulletin No. 10–02 located at *http://www.whitehouse.gov/omb/assets/bulletins/b10-02.pdf.*

This bulletin highlights three geographic areas whose principal city has changed, and therefore led to the following CBSA names all and within a 0.05 percentage point range changes and new CBSA numbers.

- Bradenton-Sarasota-Venice, FL (CBSA 14600) is replaced by North Port-Bradenton-Sarasota, FL (CBSA 35840).
- Fort Walton Beach-Crestview-Destin, FL (CBSA 23020) is replaced by Crestview-Fort Walton Beach-Destin, FL (CBSA 18880).
- Weirton-Steubenville, WV-OH Metropolitan Statistical Area (CBSA 48260) is replaced by Steubenville-Weirton, OH-WV (CBSA 44600).

The CBSAs and their associated wage index values are shown in Addendum B of this final rule. The wage index values for rural areas are shown in Addendum A of this final rule.

The following is a summary of the comments we received regarding the HH wage index proposal.

Comment: A commenter stated that the budget neutral nature of the methodology means that increases in the wage index in one area of the country necessarily result in decreases in another.

Response: By nature, the construct of the hospital wage index, in the aggregate, is to average at 1.0. Hence, the index is constructed to be budget neutral in the sense that for areas where wage index values increase, those increases are offset by decreases in other areas. The hospital wage index is based on hospital cost data and hospital utilization, and thus in the aggregate, when applied to HH utilization for the purposes of impacts, the average wage index value may not result to be exactly 1.0. For instance, as explained in the impact analysis section for this final rule, the new wage index will result in an estimated increase of $20 million in aggregate payments to HHAs in CY 2011.

Comment: A commenter stated that dropping critical access hospitals (CAHs) from the calculation of the wage index affects HHAs. As CAHs are located in rural areas, the absence of CAH wage data further compromises the accuracy, and therefore the appropriateness, of using a hospital wage index to determine the labor costs of HHAs located in rural areas.

Response: While we understand the commenter's concern, we are not able to address the comment, because the methodology regarding the pre-floor, pre-reclassified hospital wage index calculation (which we continue to believe results in an appropriate adjustment to the labor portion of the costs as required by statute), is outside of the scope of this final rule.

Comment: A commenter stated that, pending development of an industry specific wage index, CMS should investigate the impact of a population density adjustment. A population density adjustment would result in a more accurate wage adjustment that recognizes the productivity lost in time spent in traveling to provide services in less densely populated areas. CMS could simply add a population density factor by zip code during calculation of the labor portion of the payment to account for increased costs of providing services in less densely populated areas. In addition, this adjustment would reduce excess reimbursement for services provided in densely populated urban and congregate living facilities.

Response: We appreciate the commenter's comment, but we do not have evidence that a population density adjustment is an appropriate adjustment to a wage index. Section 3131(d) of the Affordable Care Act requires the Secretary to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. Because medically underserved areas may be associated with population density, the purview of the above mentioned study may possibly include feasibility of such an adjustment as part of that research. However, we note that in setting up the original HH PPS rates in 2000, we were not able to find any cost differences between rural and urban HHAs. While rural agencies cite the added cost of long distance travel to treat their patients, urban/non-rural agencies also cite added costs such as needed security measures and the volume of traffic that they must absorb. We will consider this suggestion in future research activities.

Comment: A commenter stated that the current wage index does not measure local wages accurately since the wages vary widely in some areas.

Response: The wages are measured at the local level as defined by CBSAs. HHAs are reimbursed based on the site of service of the beneficiary, using the wage index value for that area to adjust payment for geographical differences.

Comment: A commenter stated concerns regarding the use of the pre-floor, pre-reclassified hospital wage index to determine geographically relevant wages for HH workers. The commenter stated that there is a lack of

parity between different health care provider types, each of which is subject to some form of a hospital wage index, but experiences distinct actual values in their specific geographic area. Hospitals are given the opportunity to reclassify as a means of being considered to be in a geographical area with a higher wage index. HHAs are not given this option. Using the pre-floor, pre-reclassified wage index continues to put home care at a distinct disadvantage in attracting and retaining employees. Existing law permits CMS a nearly unlimited degree of flexibility to utilize a wage index that recognizes the geographic differences in labor costs in the provision of HH services across the country. Section 1895(b)(4)(C) of the Act mandates the establishment of area wage index adjustment factors, provides the Secretary discretion to determine which factors to consider, and permits the Secretary to utilize the same wage index adjustment factors that are utilized in composing the hospital wage index. The inherent inequity of HHAs competing for labor in the same service area as a reclassified hospital is similarly overdue for redress. CMS has the statutory authority to select the wage index method to be applied to HHAs and should move the wage index toward some level of comparability with that enjoyed by hospitals.

Response: The regulations that govern the HH PPS currently do not provide a mechanism for allowing providers to seek geographic reclassification. As we have explained in the past (most recently, in the CY 2010 HH PPS final rule (74 FR 58105)), the rural floor and geographic reclassification in the IPPS are statutorily authorized and are only applicable to hospital payments. The rural floor provision is provided at section 4410 of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) and is exclusive to hospitals. The reclassification provision provided at section 1886(d)(10) of the Act is also specific to hospitals.

Comment: In the current environment of deep, across-the-board cuts, the additional impact of inequitable, unpredictable, negative swings in wage index cannot be ignored any longer. Such swings are exacerbated by the current economic climate. The HH wage index is too volatile from one year to the next. CMS should develop a process that would alert HHAs to prospective swings in the hospital wage index prior to hospital wage data finalization, allowing agencies to seek intervention to eliminate or correct for missing or potentially spurious hospital cost report data on labor costs. The extra time would also allow agencies an opportunity to begin planning for changes needed to accommodate an otherwise unexpected wage index swing. At a minimum, the commenters urged CMS to put a ceiling and floor on year-to-year changes in the wage index to mitigate sudden payment changes. Another commenter asked CMS to consider applying the hospital wage index to all healthcare providers in a community. The commenter's opinion is that homecare nurses require more skills and certifications than hospital nurses and home care organizations should be able to reimburse them fairly.

Response: We have consistently used the pre-floor, pre-reclassified hospital wage index to adjust the labor portion of the HH PPS rates. The commenter is referring to rural floor and geographic reclassification provisions in the IPPS, which are only applicable to hospital payments. The rural floor provision is provided at section 4410 of the BBA and is specific to hospitals. The reclassification provision provided at section 1886(d)(10) of the Act is also specific to hospitals. As such, we continue to believe that the use of the pre-floor, pre-reclassified hospital wage index data results in the appropriate adjustment to the labor portion of the costs as required by statute.

Comment: CMS should develop and conduct a voluntary pilot test on a HH specific wage index based on non-hospital, Bureau of Labor Statistics (BLS) data calculated on a county level, rather than on the Core Base Statistical Area (CBSA) level. Several commenters stated that CMS' decision five years ago to switch from the Metropolitan Statistical Areas (MSAs) to the Core-Based Statistical Areas (CBSAs) for the wage index calculation has had serious financial ramifications for HHAs. The commenters recommend that CMS pursue a total reform of the HH wage index.

Response: As we have stated in previous rules, previous proposals to develop a HH-specific wage index were not well received by commenters or the industry. Generally, the volatility of the HH wage data and the resources needed to audit and verify that data make ensuring that such a wage index most accurately reflects the wages and wage-related costs applicable to the furnishing of HH services difficult. As such, we are not adopting a HH-specific wage index at this time. We believe that more importantly, a HH-specific wage index should be reflective of the wages and salaries paid in a specific area, be based upon a stable data source, and significantly improve our ability to determine HH payments without being overly burdensome.

In its June 2007 report titled, "Report to Congress: Promoting Greater Efficiency in Medicare", MedPAC recommended that the Congress "repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems." As such, we will continue to review and consider MedPAC's recommendations on a refined alternative wage index methodology for the HH PPS in the future. We believe that the current payment adjustment based on the CBSA areas is the best available method of compensating for differences in labor markets.

Comment: A commenter encourages CMS to analyze HH care providers both by geographic location (urban vs. rural) and by business status (for-profit vs. not-for-profit) such that Medicare payment policy can be modified to reward quality and efficiency and reduce incentives to "pad" documentation and increase revenue.

Response: We will be looking to improve the accuracy of payment to HHAs in the future, through a number of efforts. Section 3131(a) of the Affordable Care Act requires the Secretary to rebase HH payments, beginning in 2014. Factors that will be analyzed and considered include changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. In conducting the analysis for rebasing, we may consider differences between hospital-based and freestanding agencies, between for-profit and nonprofit agencies, and between the resource costs of urban and rural agencies. Additionally, section 3131(d) of the Affordable Care Act requires the Secretary to study and report on the development of HH payment revisions that would ensure access to care and payment for severity of illness. The study is to be on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. As part of this study, we are required to consult with appropriate stakeholders, such as groups representing HHAs and groups representing Medicare beneficiaries. At the conclusion of this study, we must submit a Report to the Congress by March 1, 2014. Based on the findings of this study, the Secretary may provide for a demonstration project to test whether making payment adjustments for HH services under the

Medicare program would substantially improve access to care for patients with high severity levels of illness or for low-income or underserved Medicare beneficiaries.

4. CY 2011 Annual Payment Update

a. National Standardized 60-Day Episode Rate

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

In the CY 2008 HH PPS final rule with comment period, we refined the case-mix methodology and also rebased and revised the HH market basket. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage difference, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate is 77.082 percent and the non-labor-related share is 22.918 percent. The CY 2011 HH PPS rates use the same case-mix methodology and application of the wage index adjustment to the labor portion of the HH PPS rates as set forth in the CY 2008 HH PPS final rule with comment period. Following are the steps we take to compute the case-mix and wage adjusted 60-day episode rate:

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

(2) Divide the case-mix adjusted amount into a labor (77.082 percent) and a non-labor portion (22.918 percent).

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

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

In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. The HH PPS regulations at § 484.225 set forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

For CY 2011, we proposed to base the wage index adjustment to the labor portion of the HH PPS rates on the most recent pre-floor and pre-reclassified hospital wage index. As discussed in the July 3, 2000 HH PPS final rule, for episodes with four or fewer visits, Medicare pays the national per-visit amount by discipline, referred to as a LUPA. We update the national per-visit rates by discipline annually by the applicable HH market basket percentage. We adjust the national per-visit rate by the appropriate wage index based on the site of service for the beneficiary, as set forth in § 484.230. We adjust the labor portion of the updated national per-visit rates used to calculate LUPAs by the most recent pre-floor and pre-reclassified hospital wage index. We also proposed to update the LUPA add-on payment amount and the NRS conversion factor by the applicable HH market basket update of 1.4 percent for CY 2011.

Medicare pays the 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and § 484.205(b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare would use to pay the claim.

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

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

b. Updated CY 2011 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2011 national standardized 60-day episode payment rates, we first look at the CY 2010 rates as a starting point. The CY 2010 national standardized 60-day episode payment rate is $2,312.94.

As previously discussed in section II.D. of this final rule ("Outlier Policy"), in our policy of targeting outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2011, we proposed to return 2.5 percent back into the HH PPS rates, to include the national standardized 60-day episode payment rate. Therefore, to calculate the CY 2011 national standardized 60-day episode payment rate, we first increase the CY 2010 national standardized 60-day episode payment rate ($2,312.94) to adjust for the 2.5 percent set aside in the previous year for CY 2010 outlier payments. We then reduce that adjusted payment amount by 5 percent, for outlier payments as a percentage of total HH PPS payment as mandated by section 3131 of the Affordable Care Act. Next, we update the payment amount by the CY 2011 HH market basket update of 1.1 percent.

As previously discussed in section II.A. of this final rule ("Case-Mix Measurement Analysis"), our updated analysis of the change in case-mix that is not due to an underlying change in patient health status reveals additional increase in nominal change in case-mix. Therefore, we reduce rates by 3.79 percent in CY 2011, resulting in an updated CY 2011 national standardized 60-day episode payment rate of $2,192.07. The updated CY 2011 national standardized 60-day episode payment rate for an HHA that submits the required quality data is shown in Table 4. The updated CY 2011 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data (that is, HH market basket update of 1.1 percent is reduced by 2 percentage points) is shown in Table 5.

TABLE 4—NATIONAL 60-DAY EPISODE PAYMENT AMOUNT UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2011, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

CY 2010 National standardized 60-day episode payment rate	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by The Affordable Care Act	Multiply by the home health market basket update of 1.1 percent	Reduce by 3.79 percent for nominal change in case-mix	CY 2011 National standardized 60-day episode payment rate
$2,312.94	÷ 0.975	× 0.95	× 1.011	× 0.9621	$2,192.07

TABLE 5—FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA—NATIONAL 60-DAY EPISODE PAYMENT AMOUNT UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2011, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

CY 2010 National standardized 60-day episode payment rate	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by the Affordable Care Act	Multiply by the home health market basket update of 1.1 percent minus 2 percentage points (−0.9 percent)	Reduce by 3.79 percent for nominal change in case-mix	CY 2011 National standardized 60-day episode payment rate
$2,312.94	÷ 0.975	× 0.95	× 0.991	× 0.9621	$2,148.71

c. National Per-Visit Rates Used To Pay LUPAs and Compute Imputed Costs Used in Outlier Calculations

In calculating the CY 2011 national per-visit rates used to calculate payments for LUPA episodes and to compute the imputed costs in outlier calculations, the CY 2010 national per-visit rates for each discipline are adjusted for the 2.5 percent set aside during CY 2011 for outlier payments. Then these national per-visit rates are reduced by 5 percent as mandated by section 1895(b)(3)(C) of the Act, as amended by section 3131 of the Affordable Care Act. Next, the national per-visit rates are updated by the CY 2011 HH market basket update of 1.1 percent. National per-visit rates are not subject to the 3.79 percent reduction related to the nominal increase in case-mix. The CY 2011 national per-visit rates per discipline are shown in Table 6. The six HH disciplines are as follows:

- Home Health Aide (HH aide);
- Medical Social Services (MSS);
- Occupational Therapy (OT);
- Physical Therapy (PT);
- Skilled Nursing (SN); and
- Speech Language Pathology Therapy (SLP).

TABLE 6—NATIONAL PER-VISIT AMOUNTS FOR LUPAS (NOT INCLUDING THE LUPA ADD-ON AMOUNT FOR A BENEFICIARY'S ONLY EPISODE OR THE INITIAL EPISODE IN A SEQUENCE OF ADJACENT EPISODES) AND OUTLIER CALCULATIONS UPDATED BY THE CY 2011 HOME HEALTH MARKET BASKET UPDATE, BEFORE WAGE INDEX ADJUSTMENT

Home health discipline type	CY 2010 Per-visit amounts per 60-day episode	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by The Affordable Care Act	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
				Multiply by the home health market basket update of 1.1 percent	CY 2011 per-visit payment amount f For HHAs that DO submit the required quality data	Multiply by the home health market basket update of 1.1 percent minus 2 percentage points (−0.9 percent)	CY 2011 per-visit payment amount for HHAs that DO NOT submit the required quality data
HH Aide	$51.18	÷ 0.975	× 0.95	× 1.011	$50.42	× 0.991	$49.42
MSS	181.16	÷ 0.975	× 0.95	× 1.011	178.46	× 0.991	174.93
OT	124.40	÷ 0.975	× 0.95	× 1.011	122.54	× 0.991	120.12
PT	123.57	÷ 0.975	× 0.95	× 1.011	121.73	× 0.991	119.32
SN	113.01	÷ 0.975	× 0.95	× 1.011	111.32	× 0.991	109.12
SLP	134.27	÷ 0.975	× 0.95	× 1.011	132.27	× 0.991	129.65

d. LUPA Add-on Payment Amount Update

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

The following is a summary of the comments we received regarding the LUPA add-on Payment.

Comment: Several commenters stated that at a time when costs are increasing, the LUPA "add-on reduction" will make it more difficult for agencies to deal with the additional mandates that were added to the start of care visit. This is the first time a reduction is proposed for the LUPA add-on. Costs continue to

escalate, but CMS continues to expect more while decreasing payments.

Response: We assume that the commenter is referring to either the 2.5 percent reduction to the HH PPS payment amounts due to the outlier policy legislated by section 3131(b) of the Affordable Care Act or the 1 percentage point reduction for CY 2011, 2012, and 2013 and the productivity adjustment for CY 2015 and subsequent years to the HH market basket update legislated by section 3401(e) of the Affordable Care Act; or both. As both reductions are legislated by the Affordable Care Act, we have no regulatory authority to do otherwise.

As previously discussed, we are returning 2.5 percent back into the LUPA add-on payment. We then reduce the LUPA add-on payment by 5 percent outlier adjustment as mandated by section 1895(b)(3)(C) of the Act as amended by section 3131 of the Affordable Care Act. Next, we update the LUPA payment amount by the CY 2011 HH market basket update percentage of 1.1 percent. The LUPA add-on payment amount is not subject to the 3.79 percent reduction related to the nominal increase in case-mix. For CY 2011, the add-on to the LUPA payment to HHAs that submit the required quality data will be updated by the HH market basket update of 1.1 percent. The CY 2011 LUPA add-on payment amount is shown in Table 7. The add-on to the LUPA payment to HHAs that do not submit the required quality data will be updated by the HH market basket update (1.1 percent) minus two percentage points.

TABLE 7—CY 2011 LUPA ADD-ON AMOUNTS

CY 2010 LUPA Add-On Amount Adjusted to return the outlier funds, that paid for the original 5 percent target for outliers	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by the Affordable Care Act	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
			Multiply by the home health market basket update of 1.1 percent	CY 2011 LUPA Add-On Amount for HHAs that DO submit required quality data	Multiply by the home health market basket update of 1.1 percent minus 2 percentage points (−0.9 percent)	CY 2011 LUPA Add-On Amount for HHAs that DO NOT submit required quality data
$94.72	÷ 0.975	× 0.95	× 1.011	$93.31	× 0.991	$91.46

e. Nonroutine Medical Supply Conversion Factor Update

The following is summary of the comments we received regarding the Nonroutine Medical Supplies (NRS).

Comment: A commenter stated that the calculation for the nonroutine medical supply conversion factor includes a reduction of 3.79 percent for the change in nominal case-mix weight. The commenter does not believe this reduction should be applied to the calculation of the NRS, as the NRS payment amount is not directly affected by changes in case-mix weight.

When CMS developed the refinements to the PPS payment rates effective for calendar year 2008, significant changes were made to the methodology for reimbursing of nonroutine medical supplies. The analysis performed by CMS was designed to "better match NRS payments with NRS costs." "The proposed and final regression models were developed after additional variables from OASIS items and targeting certain conditions expected to be predictors of NRS use based on clinical considerations. To account for paying of NRS through the implementation of a 6-severity group methodology, and to maintain budget neutrality, we reduce the national standardized 60-day episode payment rate (72 FR 49851 through 49852).

The standardized payment amount was adjusted to remove the cost attributed to NRS or $45.87 (72 FR 49865). Therefore, due to this change in methodology the NRS amount paid to HHAs is no longer subject to variation based upon the case-mix weight of the episode. Indeed, an episode with a case-mix of 0.5827 can receive the same NRS payment amount as an episode with a case-mix of 3.4872. Therefore, the case-mix adjustment as proposed should not be applied to the NRS payment amounts.

Response: We appreciate the commenter's perspective and input. Because our case-mix adjustment parameter comes from modeling the episode case-mix weights, not the NRS case-mix levels, we will defer the application of the 3.79 percent case-mix reduction to the NRS payment amounts for CY 2011, pending the results of an independent review of our case-mix and NRS models. Therefore, the NRS payment calculation will not be decreased by 3.79 percent for CY 2011.

Comment: A commenter stated that reimbursement for nonroutine supplies is not adequate to cover current costs for these supplies. Vendors of nonroutine supplies continue to increase costs for agencies.

Response: In our CY 2008 final rule, we implemented the now existing 6-severity group methodology for payment of NRS. As part of that implementation, we built intelligence into the HIPPS code so that we would know when supplies are being provided and when they are not, at all NRS severity levels. Since the expiration of a 6-month grace period, HHAs have been required to denote, through the HIPPS code they submit on the claim, whether supplies were actually provided to the beneficiary during that HH episode of care. As such, we will soon have the improved data on NRS, providing us with a much better capability to analyze and evaluate payment to HHAs for NRS in the future.

Payments for nonroutine medical supplies (NRS) are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. We first adjust the CY 2010 NRS conversion factor ($53.34) for the 2.5 percent set aside for outlier payments in CY 2010. We then reduce that amount by the 5 percent outlier adjustment as mandated by section 1895(b)(3)(C), as amended by section 3131(b) of the Affordable Care Act. Next, we update by the CY 2011 market basket update of 1.1 percent. As mentioned above in our summary of comments related to the NRS, we will not apply the 3.79 percent case-mix reduction to the NRS payment amounts for CY 2011. The final updated CY 2011 NRS conversion factor for CY 2011 in Table 8A. For CY 2011, the NRS conversion factor is $52.54.

TABLE 8A—CY 2011 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2010 NRS conversion factor	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by The Affordable Care Act	Multiply by the home health market basket update of 1.1 percent	CY 2011 NRS conversion factor for HHAs that do submit the required quality data
$53.34	÷ 0.975	× 0.95	× 1.011	$52.54

Using the NRS conversion factor ($52.54) for CY 2011, the payment amounts for the various severity levels are shown in Table 8B.

TABLE 8B—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM

Severity level	Points (scoring)	Relative weight	NRS payment amount
1	0	0.2698	$14.18
2	1 to 14	0.9742	51.18
3	15 to 27	2.6712	140.34
4	28 to 48	3.9686	208.51
5	49 to 98	6.1198	321.53
6	99+	10.5254	553.00

For HHAs that do not submit the required quality data, we again begin with the CY 2010 NRS conversion factor. We first adjust the CY 2010 NRS conversion factor ($53.34) for the 2.5 percent set aside for outlier payments in CY 2010. We then reduce that amount by the 5 percent outlier adjustment as mandated by section 1895(b)(3)(C) of the Act, as amended by section 3131 of the Affordable Care Act. Next, we update the conversion factor by the CY 2011 HH market basket update percentage of 1.1 percent minus 2 percentage points. The CY 2011 NRS conversion factor for HHAs that do not submit quality data is shown in Table 9A.

TABLE 9A—CY 2011 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2010 NRS conversion factor	Adjusted to return the outlier funds that paid for the 2.5 percent target for outlier payments in CY 2010	Reduced by 5 percent due to the outlier adjustment mandated by The Affordable Care Act	Multiply by the proposed home health market basket update of 1.1 percent minus 2 percentage points (−0.9 percent)	CY 2011 NRS conversion factor for HHAs that do not submit the required quality data
$53.34	÷ 0.975	× 0.95	× 0.991	$51.50

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 9B.

TABLE 9B—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM FOR HHAS THAT DO NOT SUBMIT QUALITY DATA

Severity level	Points (scoring)	Relative weight	NRS payment amount
1	0	0.2698	$13.89
2	1 to 14	0.9742	50.17
3	15 to 27	2.6712	137.57
4	28 to 48	3.9686	204.38
5	49 to 98	6.1198	315.17
6	99+	10.5254	542.06

5. Rural Add-On

The following is summary of the comments we received regarding the rural add-on policy.

Comment: Several commenters stated support for the 3 percent rural add-on to the national standardized 60-day episode rate, national per-visit rates, LUPA add-on amount, and nonroutine medical supplies (NRS) conversion factor for HH services provided in rural areas through December 15, 2015. They state that this rural add-on reflects the higher costs of rural agencies.

Response: The rural add-on is mandated by section 3131(c) of the Affordable Care Act. Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA, which was amended by section 5201(b) of the DRA. Thus the amended section 421(a) of the MMA provides an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), with respect to episodes and visits ending on or after April 1, 2010 and before January 1, 2016. The statute

waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

The 3 percent rural add-on is applied to the national standardized 60-day episode rate, national per-visit rates, LUPA add-on payment, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. We implemented this provision for CY 2010, for episodes and visits ending on or after April 1, 2010 and ending before January 1, 2011 through Program Memorandum "Temporary 3 Percent Rural Add-On for the Home Health Prospective payment System (HH PPS)" (Transmittal #674/Change Request #6955, issued April 23, 2010). Refer to Tables 10 thru 13b for these payment rates.

TABLE 10—CY 2011 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA BEFORE CASE-MIX AND WAGE INDEX ADJUSTMENT

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2011 national standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Total CY 2011 national standardized 60-day episode payment rate	CY 2011 national standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Total CY 2011 national standardized 60-day episode payment rate
$2,192.07	× 1.03	$2,257.83	$2,148.71	× 1.03	$2,213.17

TABLE 11—PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA, BEFORE WAGE INDEX ADJUSTMENT

Home health discipline type	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
	CY 2011 per-visit rate for HHAs that DO submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 per-visit rate for rural areas	CY 2011 per-visit rate for HHAs that DO NOT submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 per-visit rate for rural areas
HH Aide	$50.42	× 1.03	$51.93	$49.42	× 1.03	$50.90
MSS	178.46	× 1.03	183.81	174.93	× 1.03	180.18
OT	122.54	× 1.03	126.22	120.12	× 1.03	123.72
PT	121.73	× 1.03	125.38	119.32	× 1.03	122.90
SN	111.32	× 1.03	114.66	109.12	× 1.03	112.39
SLP	132.27	× 1.03	136.24	129.65	× 1.03	133.54

TABLE 12—TOTAL CY 2011 LUPA ADD-ON AMOUNTS FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2011 LUPA add-on amount for HHAs that DO submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 LUPA add-on amount for rural areas	CY 2011 LUPA add-on amount for HHAs that DO NOT submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 LUPA add-on amount for rural areas
$93.31	× 1.03	$96.11	$91.46	× 1.03	$94.20

TABLE 13A—TOTAL CY 2011 CONVERSION FACTOR FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2011 conversion factor for HHAs that DO submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 conversion factor for rural areas	CY 2011 conversion factor for HHAs that DO NOT submit quality data	Multiply by the 3 percent rural add-on	Total CY 2011 conversion factor for rural areas
$52.54	× 1.03	$54.12	$51.50	× 1.03	$53.05

TABLE 13B—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM FOR SERVICES PROVIDED IN RURAL AREAS

Severity level	Points (scoring)	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
		NRS payment amount for HHAs that DO submit quality data	Multiply by the 3 percent rural add-on	Total NRS payment amount for rural areas	NRS Payment amount for HHAs that DO NOT submit quality data	Multiply by the 3 percent rural add-on	Total NRS payment amount for rural areas
1	0	$14.18	× 1.03	$14.61	$13.89	× 1.03	$14.31
2	1 to 14	51.18	× 1.03	52.72	50.17	× 1.03	51.68
3	15 to 27	140.34	× 1.03	144.55	137.57	× 1.03	141.70
4	28 to 48	208.51	× 1.03	214.77	204.38	× 1.03	210.51
5	49 to 98	321.53	× 1.03	331.18	315.17	× 1.03	324.63
6	99+	553.00	× 1.03	569.59	542.06	× 1.03	558.32

E. Enrollment Provisions for HHAs

In the CY 2011 HH PPS proposed rule, we proposed several payment safeguard provisions designed to: (1) Ensure that enrolling HHAs have sufficient capital on hand to operate the business; (2) improve our ability to verify that HHAs that are changing ownership meet and continue to meet the Conditions of Participation for HHAs as specified in 42 CFR part 484; and (3) improve the quality of care that Medicare beneficiaries receive from HHAs.

1. HHA Capitalization

a. Background

As stated in the CY 2011 HH PPS proposed rule, in the January 5, 1998 **Federal Register** (63 FR 291) we published a final rule that required an enrolling HHA to furnish proof that it has available sufficient funds—or "initial reserve operating funds" (IROF)—to operate the HHA for the 3 month period following the effective date of its provider agreement. This requirement, at § 489.28, was triggered by our concern that HHAs were entering the Medicare program without sufficient funds, which could, as stated in the preamble to the January 5, 1998 final rule, have deleterious consequences on patient care. We stated therein:

> New HHAs generally are small businesses and have the same need for adequate capitalization as have other small businesses, which are just starting. As with other small businesses, a lack of funds in reserve to operate the business until a stream of revenues can be established can seriously threaten the viability of the business. In addition, for new HHAs, which are in business to render patient care services, any condition threatening the viability of the new business can adversely affect the quality of care to their patients and, in turn, the health and safety of those patients. That is, if lack of funds forces an HHA to close its business, to reduce staff, or to skimp on patient care services because it lacks sufficient capital to pay for the services, the overall well-being of the HHA's patients could be compromised. In fact, there could be the risk of serious ill effects as a result of patients not receiving adequate services.

In the January 5, 1998 preamble, we also cited a 1997 OIG report entitled, "Home Health: Problem Providers and their Impact on Medicare" (OEI–09–96–00110), in which the OIG expressed similar concerns about undercapitalized HHAs. The OIG stated:

> If it were not for Medicare accounts receivable, problem agencies would have almost nothing to report as assets. Agencies tend to lease their office space, equipment, and vehicles. They are not required by Medicare to own anything, and they are almost always undercapitalized. On average, cash on hand and fixed assets amount to only one-fourth of total assets for HHAs, while Medicare accounts receivable frequently equal 100 percent of total assets. These agencies are almost totally dependent on Medicare to pay their salaries and other operating expenses. For a home health agency, there are virtually no startup or capitalization requirements. In many instances, the problem agencies lease everything without collateral. They do not even have enough cash on hand to meet their first payroll.

We noted in the CY 2011 HH PPS proposed rule that our Medicare contractors have traditionally determined the provider's compliance with the capitalization provisions in § 489.28 prior to making their recommendation for approval to the State Agency and CMS Regional Office (RO). This can occur many months before the HHA signs its provider agreement. To ensure that the HHA maintains its required level of capitalization during this potentially lengthy period—as well as during the period between when it signs said agreement and the time it is granted Medicare billing privileges (a period which also can last several months)—we proposed at § 489.28(a) to require the HHA to "have available sufficient funds * * * at the time of application submission and at all times during the enrollment process to operate the HHA for the 3 month period after Medicare billing privileges are conveyed by the Medicare contractor."

We believe that confirming capitalization more than once during this process would address our concern that a provider may have redirected these funds—which were originally secured exclusively to meet the capitalization requirements—for a purpose other than to operate the business. Indeed, situations have arisen in which an HHA no longer has sufficient capitalization at the time it is enrolled in Medicare. This defeats the policy behind § 489.28, which is to ensure that HHAs are adequately capitalized when they become Medicare providers. Accordingly, we believe that a prospective HHA must meet and maintain adequate capitalization during the entire period between when it submits its enrollment application to the Medicare contractor up to 3 months after the contractor conveys Medicare billing privileges to the HHA. This will ensure that the HHA has sufficient operating funds at the time of application submission, during the period in which a State Agency or deemed accrediting organization is ensuring that the HHA meets the Conditions of Participation, and when Medicare billing privileges are conveyed.

b. Proposed Provisions

We proposed the following provisions related to capitalization:

- In § 424.510, we proposed to add the IROF requirement specified in § 489.28(a), so as to make it an enrollment requirement for prospective HHAs.
- In § 424.530(a)(8), we proposed to deny Medicare billing privileges to a prospective HHA if it could not furnish supporting documentation (within 30

days of a CMS or Medicare contractor's request) verifying that it met the IROF requirement specified in § 489.28(a). We also proposed to deny Medicare billing privileges to a prospective HHA that failed to meet the IROF requirement at § 489.28(a).

- In § 424.535(a)(11), we proposed to revoke Medicare billing privileges and the corresponding provider agreement if the enrolled HHA was not able to furnish supporting documentation (within 30 days of a CMS or Medicare contractor's request) verifying that it met the IROF requirement specified in § 489.28(a).
- In § 489.28(a), we proposed to require that the HHA have available sufficient IROF at the time of application submission, and at all times during the enrollment process to operate the HHA for the 3 month period after Medicare billing privileges are conveyed by the Medicare contractor (exclusive of actual or projected accounts receivable from Medicare).
- In § 489.28(c), we proposed to add a new paragraph (1) to reemphasize that the Medicare contractor, in selecting comparative HHAs for the purpose of calculating the enrolling HHA's required level of capitalization, could only select HHAs that submitted cost reports to Medicare.
- In § 489.28(g)(1), we proposed to establish that CMS may deny Medicare billing privileges to an HHA unless the HHA meets the initial reserve operating funds requirements of this section.
- In § 489.28(g)(2), we proposed to establish that CMS may revoke the Medicare billing privileges of an HHA that fails to meet the initial reserve operating funds requirements of this section within three months of receiving its billing privileges.

c. Analysis of and Responses to Public Comments

The following is a summary of the comments received on our proposed capitalization provisions, and our responses thereto:

Comment: Several commenters expressed support for our proposal to require multiple instances of capitalization verification between the time an application is submitted up to 3 months after the contractor conveys Medicare billing privileges. One commenter stated that the proposed capitalization requirement would reduce the risk that incoming providers will have inadequate funds to operate. The commenter added that the provider enrollment process can take several months or more; thus, expanding Medicare's authority to verify the IROF more than once is a reasonable safeguard. Another commenter stated that the proposed capitalization requirements are important to ensure that new HHAs have adequate resources to provide quality care to patients.

Response: We appreciate the support of these commenters.

Comment: One commenter stated that the signing of a provider agreement signifies that the HHA has met the requirements to receive payment. The commenter also stated that proposed § 489.28(g)(2) allows CMS to enter into a provider agreement before verification of capitalization is performed at the point that billing privileges are conveyed. From this, the commenter seemed to imply that verification of capitalization after the conveyance of a provider agreement is inappropriate, since the provider has already—via the provider agreement—been deemed to have met the Medicare requirements for participation, including the capitalization requirements. The commenter recommended that we: (1) Verify the IROF at the time of enrollment, the time of the initial survey, and the time the provider agreement is signed; and (2) delete proposed § 489.28(g)(2), as it conflicts with § 489.28(g)(1), which does not allow CMS to convey billing privileges until IROF requirements have been met.

Response: In the August 16, 2010 final rule titled, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System Changes and FY 2011 Rates; Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services; Medicaid Program: Accreditation for Providers of Inpatient Psychiatric Services; Final Rule," we revised the effective date of provider and supplier agreements at § 489.13. Specifically, section 489.13 was revised to clarify that the date of a Medicare provider or supplier approval may not be earlier than the latest date on which all applicable Federal requirements have been met, and that such requirements include review and verification of an application to enroll in the Medicare program by CMS's legacy fiscal intermediary, legacy carrier, or Medicare Administrative Contractor (MAC). These clarifications were necessary because a September 28, 2009 decision of the Appellate Division of the Department of the Appeals Board (DAB) that interpreted § 489.13 as not including enrollment application processing among the Federal requirements that must be met.

Accordingly, the August 16, 2010 final rule mentioned above revised § 489.13(b) to state," Federal requirements include, but are not limited to—

(1) Enrollment requirements established in Part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in § 489.10 and § 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification."

Thus, Medicare billing privileges are conveyed by the Medicare contractor, not through the issuance of a provider agreement. That is, even though the provider has signed a provider agreement, the provider must, after that point, still continue to meet all enrollment requirements before the contractor conveys Medicare billing privileges. Moreover, as stated in this final rule, one of those requirements is the maintenance of adequate capitalization. In fact, even after billing privileges are conveyed, the provider must meet the capitalization requirement for another 3 months. This is consistent with the Medicare enrollment requirement in 42 CFR 424.500 *et seq.* that the provider remain in compliance with all enrollment requirements once it is enrolled in Medicare.

With respect to the commenter's request to delete § 489.28(g)(2) because it conflicts with § 489.28(g)(1), we believe there is no conflict. Section § 489.28(g)(2) provides that the capitalization requirements be maintained for 3 months after billing privileges are conveyed—much like the requirement that the provider continue to meet other enrollment requirements after it is enrolled in Medicare. Section § 489.28(g)(1), on the other hand, provides that capitalization requirements must be met before billing privileges are conveyed. The provisions, in other words, are not mutually exclusive. They simply cover two different timeframes.

Nevertheless, to alleviate any confusion on this issue, we have revised § 489.28(a) to reemphasize that the HHA must maintain capitalization during the 3 month period following its receipt of Medicare billing privileges.

Comment: Several commenters stated that if CMS intends for HHAs to

maintain capitalization 3 months after they are able to bill Medicare, this does not comport with the provisions of § 489.28(g), even after these provisions are changed pursuant to this rule. This is because § 489.28(g) will still state that CMS will only convey Medicare billing privileges to an HHA that satisfies its IROF requirement. Another commenter also requested clarification on how our proposed changes are consistent with the current verbiage in § 489.28(g).

Response: As indicated in our response to the previous commenter, the HHA will still be required to satisfy the IROF requirement before receiving Medicare billing privileges. However, the HHA will also be required to maintain the IROF level during the first 3 months after receiving billing privileges. These two requirements, again, are not inconsistent, but merely address two different timeframes. We have revised § 489.28(a) to make this point more clear.

Comment: One commenter stated that the new capitalization rules could hinder the creation of new HHAs, which, in turn, could harm underserved areas, and that the closure of a new HHA because of the new requirements could disrupt patient care. The commenter recommended flexibility and discretion in applying the capitalization requirements when the HHA's failure to meet the required IROF levels is superseded by the need for the HHA in that community, or when the HHA's financial condition on a prospective basis suggests that it will likely become financially viable.

Response: While we understand and appreciate the commenter's concerns, we feel, for reasons already stated, that it is important for incoming HHAs to meet and maintain the capitalization amount specified by the Medicare contractor at the time of enrollment, throughout the enrollment process, and during the first 3 months after Medicare billing privileges are conveyed. We note, moreover, that if a HHA's Medicare billing privileges are denied or revoked for failing to meet the capitalization requirements, the HHA is afforded administrative appeal rights pursuant to the procedures set forth in 42 CFR part 498.

Comment: One commenter stated that it is unclear whether CMS will require HHAs to show capitalization more than 3 months after they are able to bill the Medicare program.

Response: Section 489.28(a) of the final rule states that the HHA must maintain capitalization up to 3 months after Medicare billing privileges have been conveyed to the provider.

Comment: One commenter stated that the proposed provisions lack clarity as to when an HHA will be required to show capitalization.

Response: We believe that § 489.28(a) is clear as to the points at which proof of capitalization must be shown.

Comment: One commenter recommended that CMS ensure there is transparency throughout the capitalization process. Specifically, the commenter urged CMS to make certain that the applicant: (1) Is able to determine how much capitalization is needed at the time it submits its application through the last stage of the review process; (2) is notified if or when the capitalization amount changes and give the applicant sufficient time to secure any capitalization shortfall; and (3) is subject to capitalization standards that are evidence-based and reviewable by an objective and independent person or entity. Another commenter recommended that CMS require each contractor to: (1) Publish the methodology used to calculate IROF levels for a particular region or State; (2) use current cost report data for each calendar year; and (3) publish ranges of IROF based on current cost report data.

Response: We will ensure that: (1) Sufficient information is available to HHAs prior to submitting their enrollment applications so they know what the appropriate capitalization levels are and the justification for and basis behind them; (2) incoming HHAs are notified when their required capitalization amounts change; and (3) our Medicare contractors calculate the IROF amount consistent with existing regulations and the provisions in this final rule. Moreover, we expect that our contractors will make annual adjustments to the IROF to ensure that the capitalization amount is based on current full cost report data.

Comment: One commenter indicated that the proposed clarification in § 489.28(c)(1) regarding the use of cost reports when selecting comparative HHAs is superfluous, since § 489.28(c) is already clear on this point.

Response: Though we agree that § 489.28(c) already discusses this topic, we have clarified in this final rule that Medicare contractors will use full cost report data to calculate the IROF amount. As such, Medicare contractors will exclude from the IROF calculation those HHAs that do not submit cost report data or that submit low utilization cost report data, as defined in existing program guidance.

Comment: A commenter stated that § 489.28(a) holds that the IROF is to be used to operate the HHA for the 3 month period after its Medicare provider agreement becomes effective. Requiring an HHA to show proof of IROF 3 months after billing privileges have been conveyed will not allow the agency to use these funds as intended by the rule.

Response: We do not agree that the HHA would be unable to use these funds during the first 3 months of operations. Section 489.28(a) simply states that the provider must have adequate capitalization on hand to operate the business for the 3 month period after billing privileges are conveyed.

Comment: One commenter stated that the need to show capitalization three times places a tremendous financial burden on prospective HHAs that are providing care to patients while awaiting reimbursement approval.

Response: We believe this comment underscores our concern about undercapitalized HHAs enrolling in Medicare. Moreover, since most businesses receive monthly banking statements or have ready access to information about their financial net worth, we do not believe that it is burdensome to furnish this information upon a Medicare contractor's request.

2. HHA Changes of Ownership

a. Background

In the CY 2010 HH PPS proposed rule, we also addressed the issue of HHA "flipping" (*e.g.,* rapidly selling the HHA), or the HHA "certificate mill" process. We explained in detail how this process works and our concerns about it in the preamble to that August 13, 2009 rule (74 FR 40948):

> We have recently found instances where owners of a HHA, some of which were working in concert with brokers or organizations operating 'turn-key' businesses, have enrolled or have attempted to enroll in the Medicare program for the specific purpose of selling the Medicare billing privileges and the Medicare provider agreement of their HHA to a third-party. In this scenario, the buyer or seller of the HHA typically would notify Medicare of the sale or change of ownership via the Medicare enrollment application (CMS–855A) after the billing privileges have been transferred when the HHA is sold.
>
> Current CMS policy recommends surveys when there is a change of ownership. However, surveys in cases of a change of ownership do not occur with the frequency that they do when providers initially enroll in Medicare. Consequently, there are instances in which a change of ownership takes place yet the new owner does not undergo a survey, in which case Medicare cannot conclusively ascertain whether the business, under new ownership, meets the Conditions of Participation under 42 CFR part 484. This serves as an incentive for certain prospective providers to enroll in the

Medicare program with the sole purpose of transferring Medicare billing privileges and the associated provider agreement when the business is sold.

This is problematic for two reasons. First, the prospective provider has minimal incentive for ensuring quality care for its patients after it is enrolled because its exclusive objective for participating in Medicare in the first place is to sell the business shortly after receiving Medicare billing privileges. In other words, the provider, aware that it may be able to sell the business without the HHA having to undergo a survey, may have little motivation to ensure that it is in compliance with the Conditions of Participation under 42 CFR part 484, since it intends on selling the business in any event. Medicare beneficiaries, therefore, may receive inadequate services as a result of this activity. Second, without the protection that a survey provides, the HHA may attempt to bill Medicare for these insufficient services. These circumstances increase the risk for an HHA to submit inappropriate and potentially fraudulent claims to Medicare, which places the Medicare Trust Funds at risk.

In short, under this scenario, entrepreneurs apply for Medicare HHA certification, undergo a survey, and become enrolled in Medicare, but then immediately sell the agency. These brokers, in other words, enroll in Medicare exclusively to sell the HHA, rather than to provide services to beneficiaries. This practice allows a purchaser of an HHA to enter the Medicare program through the back door—via the change of ownership process—without having to undergo a State survey. Because of this circumvention of the State survey process, we have no way of knowing whether the HHA, under its new ownership, is still in compliance with the HH conditions of participation.

Largely to address this concern, we proposed in § 424.550(b)(1) of the CY 2010 HH PPS proposed rule that if an owner of an HHA sells (including asset sales or stock transfers), transfers or relinquishes ownership of the HHA within 36 months after the effective date of the HHA's enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead: (1) Enroll in the Medicare program as a new HHA under the provisions of § 424.510; and (ii) obtain a State survey or an accreditation from an approved accreditation organization.

We received several comments supporting the establishment of this "36 month rule" and did not receive any specific recommendations that we establish exceptions thereto. We therefore left § 424.550(b)(1) largely intact in the 2010 HH PPS final rule. However, we did reiterate in that rule that the 36-month provision was not only designed to deal with the specific issue of "flipping," but to also address the broader problem of new owners of HHAs entering the program without a State survey being performed:

> We wish to make clear that the intent of 42 CFR § 424.550(b)(1) goes beyond the issue of "turn-key" operations. If an HHA undergoes a change of ownership, CMS—at the current time—generally does not perform a State survey pursuant thereto. CMS therefore has no sure way of knowing whether the HHA, under its new ownership and management, is in compliance with the HHA conditions of participation—regardless of whether the ownership change occurred 12, 24, or 36 months after the HHA's initial enrollment. Unless CMS can make this determination, there is a risk that the newly-purchased HHA, without having been appropriately vetted via the survey process, will bill for services when it is out of compliance with the conditions of participation. And in light of the frequency of inappropriate practices, as outlined in the GAO report, of HHAs relative to other provider types, we believe it is imperative that we ensure that the newly-purchased HHA be subject to an appropriate level of review. (74 CFR 58118)

The effective date of § 424.550(b)(1) was January 1, 2010.

b. Proposed Provisions

After the implementation of § 424.550(b)(1), we received a number of comments regarding the impact of this provision on bona fide ownership transactions. Therefore, in this year's HH PPS proposed rule, we proposed to revise § 424.550(b)(1), and to establish several exceptions:

- In § 424.502, we defined the term "change in majority ownership" to mean when an individual or organization acquires more than a 50 percent interest in an HHA during the 36 months following its initial enrollment into the Medicare program or a change of ownership (including asset sales, stock transfers, mergers, or consolidations). This would include an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, and mergers during a 36 month period.
- In § 424.550(b)(1), we proposed that any change in majority ownership within 36 months after the effective date of the HHA's enrollment in Medicare (including asset sales, stock transfers, mergers or consolidations) would require the entity to enroll as a new HHA and undergo a State survey or obtain accreditation.
- In § 424.550(b)(2)(i), we proposed to exempt from § 424.550(b)(1) a publicly-traded company that is acquiring another HHA, and both entities submitted cost reports to Medicare for the previous 5 years.
- In § 424.550(b)(2)(ii), we proposed to exempt from § 424.550(b)(1) an HHA parent company that is undergoing an internal corporate restructuring, such as a merger or consolidation, and the HHA submitted a cost report to Medicare for the previous 5 years.
- In § 424.550(b)(2)(iii), we proposed to exempt from § 424.550(b)(1) those situations where the owners of an existing HHA are changing its existing business structure (for example, partnership to a limited liability company; sole proprietorship to subchapter S corporation), but the individual owners remain the same and there is no change in majority ownership.
- In § 424.550(b)(2)(iv), we proposed to exempt from § 424.550(b)(1) those ownership changes involving the death of an owner who owns a 49 percent or less interest in an HHA (where several individuals or organizations are co-owners of an HHA and one of the owners dies).

We proposed these exceptions to account for certain legitimate transactions that might be unduly affected by the 36-month rule. However, as we stated in the proposed rule, our decision to do so in no way alleviated our ongoing concerns about the "certificate mill" process. We also remained concerned about the broader ability of new HHA owners to enter Medicare through the back door via the change of ownership process, as opposed to the initial enrollment and State survey mechanism.

c. Analysis of and Responses to Public Comments

The following is a summary of the comments received regarding the 36-month rule, and our responses thereto:

(1) General Application of Rule

Comment: One commenter expressed support for the 36-month rule, as well as for our proposed changes and exceptions. The commenter stated that the rule is one means to reduce the number of new HHAs that: (1) Are entering Medicare ill-equipped to provide high-quality care; and (2) easily fall into patterns of behavior that hurt the integrity of the Medicare program. Another commenter stated that the additional clarification to the 36-month rule was positive.

Response: We appreciate and agree with these comments.

Comment: One commenter stated that the survey of an HHA that has changed owners would seem appropriate. New

owners/operators may not be well-educated on home care rules and regulations, and surveys of such agencies would often be in the patients' best interests. Exceptions might be considered when another already-certified and operating HHA with a proven track record purchases another HHA. Still, care transitions and managerial changes can place patient care at risk. Timely and targeted surveys may avoid many problems later on, both for the purchased HHA and its patients.

Response: We appreciate this comment, and share the commenter's belief that surveying new owners would be in the best interests of the HHA's patients.

Comment: Several commenters recommended that we limit the applicability of the 36-month rule to ownership changes occurring within 36 months after the effective date of the HHA's initial enrollment in Medicare, rather than within 36 months after the HHAs most recent ownership change. One commenter added that this single change would eliminate the most significant problems created by the proposed rule.

Response: We believe that applying § 424.550(b)(1) to ownership changes that occur within 36 months of: (1) Initial enrollment and (2) the HHA's most recent ownership change, is needed to ensure that newly-sold HHAs are in compliance with the conditions of participation.

Comment: Several commenters recommended that we rescind the current 36-month rule and establish a technical advisory committee with experts from home care and the finance sector to establish guidelines that will ensure that patient care remains the top priority for existing and new home care agencies.

Response: We disagree that a technical advisory committee is needed to address the provisions of the 36-month rule. We believe that the comments received in response to our proposal and our subsequent changes will result in improved patient care and financially viable HHAs.

Comment: Several commenters stated that the proposed provisions constitute an expansion of the 36-month rule that would block new investments in the HH industry, which, in turn, could inhibit necessary industry consolidation and prevent providers from expanding. The commenters generally believed that the costs of the proposed revisions outweigh any benefits to the Medicare program or its beneficiaries. Another commenter stated that revising the rule to ensure that capital is available will lead to better patient care outcomes, fewer issues in the operations of HHAs, and increased innovations that will lower the overall costs of care.

Response: We disagree with the assertion that the costs of the proposed rule outweigh its benefits. Beyond the issue of "certificate mills" and HHAs' "flipping" ownership to a third-party, we remain concerned about: (1) The sale or transfer of HHAs that have little or no enterprise value except the Medicare billing number, and (2) new owners entering Medicare without the HHA having to undergo a State survey.

Comment: Several commenters stated that for many HHAs that have been enrolled in Medicare for more than 36 months (or even less than 36 months), the proposed rule will deprive them of access to capital, in that no existing HHA can afford to lose its Medicare participation until a new survey is conducted, a process which can take many months. No ongoing business, the commenters stated, can continue to incur expenses with no revenue during that time, and that patient care could therefore suffer. Several commenters further contended that by expanding the rule to apply to changes occurring more than 36 months after initial enrollment, banks will not loan money to, private equity firms will not invest in, and quality HHA organizations will not purchase, existing HHAs. This is because the bank/purchaser realizes it will be unable to effectively (a) foreclose upon, or (b) sell its majority interest in the business, due to the need to enroll as a new provider and undergo a survey. The commenters stated that some financiers have, since the implementation of § 424.550(b)(1), declined to loan money to HHAs because of these concerns, with one commenter adding that this closing of access to funds does not help address the issue of "flipping." One commenter added that CMS should not require enhanced capitalization in one section of the proposed rule while denying access to that capital in another. Another commenter stated that many entities will avoid the HHA business entirely if they cannot exit their investment for 36 months or obtain capital. Meanwhile, enrolled HHAs, another commenter noted, will be reluctant to exit Medicare, which could prove problematic for Medicare if the HHA is poorly-performing or of low-quality. Another commenter stated that lenders already perform due diligence on the HHA before loaning it money. This important safeguard is lost if lenders will not loan funds to the HHA because of the 36-month rule.

Response: As already stated, the 36-month rule is designed to ensure that enrolled HHAs comply with the HHA conditions of participation and furnish quality services to Medicare beneficiaries. Nevertheless, we have adopted, as explained below in more detail, certain exceptions to the 36-month rule. We believe these exceptions will help ensure that HHAs are able to obtain financing, while at the same time protecting the integrity of the Medicare program.

Comment: One commenter suggested that rather than require an HHA to reenroll in Medicare, the entity should instead have to obtain re-accreditation from an approved accreditation organization within 6 months of the ownership change. If reaccreditation is obtained within this period, the reenrollment process should not be required. If reaccreditation is not obtained, reenrollment would be necessary. The commenter believed that the reaccreditation process would be a faster and more cost-effective way to identify and stop the certificate mill process, and would not result in a gap in reimbursement for legitimate HHAs or a reduction in services for patients. Another commenter stated that the HHA should still be able to bill Medicare while awaiting the survey. This will prevent a disruption of services.

Response: Though we appreciate these comments, our concern is that during the period in which the HHA is waiting for the survey to be performed, an entity that is potentially out of compliance with the conditions of participation because of its ownership change may be billing Medicare for services it is not qualified to provide. Accordingly, we are not adopting these recommendations.

Comment: A commenter stated that although the survey requirement of the 36-month rule is essentially based on the old owner's conduct—that is, the owner's sale of its HHA—it is the new owner that must undergo the survey. The commenter believed this was somewhat unfair.

Response: We disagree. In the commenter's scenario, the buyer is voluntarily agreeing to purchase the HHA. If a prospective buyer is uncomfortable with undergoing a survey, it need not proceed with the sale. Moreover, by ensuring that the HHA has submitted full cost reports, we believe this information will assist the buyer in establishing a fair valuation for the HHA it is purchasing.

Comment: One commenter questioned the value of § 424.550(b)(1) on two grounds. First, if an owner has operated a Medicare-enrolled HHA for at least 36 months, it is clear that it is not a broker looking to immediately "flip" the HHA

after enrollment. Second, an HHA can easily circumvent the 36-month rule by simply not disclosing the ownership change; the commenter suggested that by the time CMS learns of the transaction, it may be too late. Several commenters contended that the rule is only triggered when the HHA self-reports the change in ownership to CMS. Legitimate businesses that are willing to self-report under these circumstances are not the types of entities that generally pose a risk to Medicare. It therefore follows that the 36-month rule will prevent only legitimate transactions from taking place. Another commenter stated that if an HHA is enrolled for more than 36 months, this should be adequate proof that the entity is not a certificate mill. Hence, the rule should only apply to the first 36 months of enrollment.

Response: With respect to the first comment, we have, as previously mentioned, elected to apply § 424.550(b)(1) to ownership changes that occur within 36 months of: (1) Initial enrollment, and (2) the HHA's most recent ownership change. Again, our concerns go beyond the issue of "flipping," and touch on the larger question of whether a newly-sold HHA is still in compliance with the conditions of participation.

Regarding the remaining comments, we note that—under the Medicare enrollment regulations at 42 CFR 424.500 *et seq.*—a failure to report an ownership change to CMS can result in a: (1) Retroactive revocation of the provider's Medicare billing privileges, and (2) a bar against reenrolling in Medicare for a period of 1 to 3 years. Hence, it is to the provider's advantage to self-report the ownership change, for failing to do so could keep the provider out of Medicare for a much longer period if the provider's billing privileges are revoked. Moreover, § 424.550(b)(1) is triggered when the change of ownership occurs, rather than whether it is reported. In other words, it is not the submission of a CMS–855A ownership change application that implicates § 424.550(b)(1), but the ownership change itself.

Comment: Several commenters stated that § 424.550(b)(1) was inconsistent with section 1891(c)(2)(B)(i) of the Act. They contended that Congress did not intend for State surveys to take place every time there is a change of ownership, and that if a survey was nevertheless necessary, it had to occur within 2 months of the change. The commenters believed that CMS has therefore exceeded the authority provided to the Secretary under section 1891(c)(2)(B)(i).

Response: We disagree. Nothing in the statute itself prohibits us from enacting § 424.550(b)(1). Section 1891(c)(2)(B)(i) gives CMS the discretion to perform a survey within 2 months if a change of ownership has occurred. This issue was discussed in the legislative history of this provision, which read in part:

> The Committee amendment would *authorize* the States and the Secretary to conduct a standard survey, or an abbreviated version of a standard survey within 2 months after any change in ownership, administration, or management of a facility, as well as after a change in the director of nursing. (H.R. Rep. 100–391(I), 1987 U.S.C.C.A.N. 2313–1) (Emphasis added).

However, as both the statute and the aforementioned language indicate, we are not *mandated* to take this action within the 2 month period. In addition, while we appreciate the need for surveys in such situations to be conducted as rapidly as possible, State survey workloads generally do not permit them to happen within 2 months of the change.

Comment: Several commenters stated that instead of requiring a new enrollment and survey—a process which could take an extended period of time—CMS should use its authority under section 1891(c)(2)(B)(i) to conduct a survey of a sold HHA within 2 months of the sale's effective date. They added that the § 424.550(b)(1) survey requirement will further burden State survey agencies and accreditation organizations. In light of this, they questioned the need for such surveys if both the buyer and seller are legitimate businesses, as shown by their submission of cost reports for 36 months.

Response: While we appreciate this suggestion, the commenters seem to imply that we do not have the authority to conduct a survey outside of that referenced in section 1891(c)(2)(B)(i) of the Act. As already indicated, we do not agree. We further note that a survey performed pursuant to § 424.550(b)(1) is of a new HHA, not an existing one; this is because § 424.550(b)(1) requires the HHA to enroll as a new provider.

Comment: One commenter suggested that CMS hold that an HHA provider number will not transfer upon an ownership change unless either: (1) The new owner has successfully been through the State survey or accreditation process and the parent company has filed cost reports on behalf of other HHAs it owns for 36 months; or (2) the HHA being purchased has filed cost reports for at least 36 months. This would, the commenter explained, significantly curtail, if not eliminate, the certificate mill process.

Response: As already explained, our concerns are not limited to the "flipping" process. We are also concerned with ensuring that newly-sold HHAs are still in compliance with the conditions of participation. Nevertheless, we have adopted an exception to the 36-month rule that is consistent with the commenter's second suggestion.

Comment: Several commenters stated that the primary intent of this provision was to stem the practice of turn-key ventures that establish HHAs for the sole purpose of selling them. The commenters argued that the proposed rule exceeds this intent.

Response: We disagree that this rule exceeds its intent. Again, aside from the issue of "flipping," we believe it is crucial for Medicare to ensure that entities undergoing an ownership change remain in compliance with the conditions of participation. We believe the final rule helps fulfill this intent.

Comment: One commenter stated that the proposed changes are confusing and discriminatory, that the rule conflicts with existing law regarding transfers of ownership, and will effectively halt all mergers and acquisitions in the HH industry unless the HHA is a public company. The commenter stated that many HHAs are small companies, and their investment in our communities should be protected.

Response: We are unable to address the commenter's first and second contentions, as the commenter did not explain how the proposed rule is confusing or discriminatory, or how it is inconsistent with current laws regarding ownership changes. With respect to the third contention, we agree that the volume of HHA ownership changes, including asset sales and stock transfers, could be reduced as a result of the 36-month rule. Yet we also believe that the exceptions outlined in this final rule will allow a number of legitimate HHA ownership changes to proceed.

Comment: Several commenters stated that no evidence of the "certificate mill" problem has been substantiated by CMS. Another commenter stated that CMS has not defined or described the program integrity or quality of care concerns that the proposed rule is designed to address, nor has CMS identified the harm caused by the "flipping" process. This commenter added that if CMS's concerns go beyond the issue of "flipping," this needs to be clearly disclosed so that comments can be furnished.

Response: We disagree with these assertions. In the proposed and final rules for CY 2010 and 2011, we clearly articulated our concerns about this

problem and stated that we have uncovered instances where entities have enrolled in Medicare for the specific purpose of selling their HHAs to other entities looking to obtain Medicare billing privileges. We further explained that this practice allows a new entity to enter Medicare without having to undergo a State survey, which therefore raises questions as to whether the HHA is furnishing quality services to Medicare beneficiaries. In the 2010 proposed and final rules, we also articulated why this issue is especially disconcerting in light of the program integrity issues prevalent in the HHA community. In addition, we have consistently explained our concerns about the need to verify that newly-sold HHAs—even those not specifically engaged in the practice of "flipping"—are in compliance with the conditions of participation.

Comment: One commenter stated that a change in majority ownership does not necessarily imply a change in the management of the HHA's day-to-day operations. A survey should be conducted only if the majority ownership change is accompanied by other factors that raise questions about the entity's compliance. In other words, surveys pursuant to § 424.550(b)(1) should be conducted on a case-by-case basis. Other commenters, too, expressed concern about the "majority ownership" standard, and stated that CMS should instead apply the definition of "change of ownership" in § 489.18 to the 36-month rule, or should require a 100 percent ownership change before § 424.550(b)(1) is triggered.

Response: While we agree that a change in majority ownership of a particular HHA may not always result in a change in the HHA's management, it has been our experience that a change in management routinely occurs when there is a change in ownership.

Comment: Several commenters recommended that the proposed revisions to the 36-month rule be applied prospectively only. Specifically, the commenters believed that no currently-enrolled HHA should be subject to the rule, in that they entered Medicare without a restriction on the sale of the HHA other than those existing at that time. At most, one commenter stated, CMS should apply the rule to HHAs initially enrolled in Medicare on January 1, 2010 (the effective date of the rule) or later. Otherwise, applying the rule to HHAs enrolled prior to that point will affect the business's value and financial stability.

Response: For reasons already stated, it is important for us to confirm that an entity undergoing an ownership change is still in compliance with the HHA conditions of participation. Consequently, we do not believe that all HHAs enrolled prior to January 1, 2010 should be exempt from the provisions of this final rule. As an example, assume that an HHA initially enrolled in Medicare on July 1, 2009. The HHA is subject to § 424.550(b)(1) through July 1, 2012, or 36 months after its date of initial enrollment. If the HHA undergoes a change in majority ownership on September 1, 2011, it will be subject to § 424.550(b)(1) until September 1, 2014, or 36 months after its most recent ownership change.

Comment: Several commenters expressed concern that § 424.550(b)(1) would lead to beneficiaries that are under treatment by an HHA undergoing a § 424.550(b)(1) ownership change to be denied certain services (or discharged and compelled to find care elsewhere), since the HHA will have to enroll as a new entity. Another commenter stated that this could also lead to layoffs of the HHA's staff.

Response: We disagree. As we have stated in a number of forums, there is no shortage of available HH services throughout the country. A patient who may be discharged under the commenter's scenario will retain access to care via other HHAs within the community. We do not think there is a risk of a discharged beneficiary being unable to obtain HHA services from another provider.

Comment: A commenter suggested that instead of the 36-month rule, CMS should use its deactivation authority under § 424.540 to deactivate the billing privileges of an entity undergoing a change of ownership until a State survey is completed; additional ownership changes could be prohibited during that period. The new owner would therefore receive payments, but they would be delayed. This would be consistent with § 424.540(b)(3)(i), which mandates a survey prior to the reactivation of an HHA's billing privileges. Likewise, another commenter suggested that CMS, in the alternative: (1) Require an HHA to notify CMS of the forthcoming sale 60 days in advance (and terminate the HHA if such notice is not given); (2) suspend the HHA's billing privileges effective the date of the sale; and (3) require the HHA to undergo a State survey or obtain accreditation within 6 months of the ownership change. Failure to meet either (1) or (3) would result in the termination of the provider's Medicare enrollment.

Response: We appreciate these suggestions. However, we believe that § 424.550(b)(1) more adequately furnishes the program safeguards we seek because the HHA will be required to enroll as a new provider and be subject to all of the provider enrollment and State survey vetting processes that other new HHAs must undergo.

Comment: Another commenter suggested that CMS mandate that a provider agreement would not transfer upon a change of ownership if both the purchasing and selling entities: (1) Have not successfully been through the State survey process (or deemed accreditation process); and (2) have never filed an HHA cost report.

Response: We appreciate this suggestion. The commenter's first criterion, however, is superfluous because the enrolled HHA that is being purchased will have already gone through the State survey or accreditation process prior to enrollment. Moreover, the second criterion makes no distinction between full cost reports and low or no utilization cost reports. Consequently, under the commenter's scenario, an HHA could be exempt from the 36-month rule so long as it submitted one cost report—even if it was a no utilization cost report. In light of this, we do not believe the commenter's recommendation provides the necessary program safeguards.

Comment: One commenter stated that while the 36-month rule was well-founded in purpose and intent, it will negatively impact bona fide HHAs and the patients they serve and should be redesigned wholesale or significantly revised to better balance the interests of patients, providers, and Medicare. The commenter recommended that CMS work with the health care industry to achieve the program integrity purposes behind the rule.

Response: We believe the exceptions in this final rule strike the necessary balance between our program integrity concerns and our desire to address some of the issues raised by the HHA industry.

Comment: One commenter stated that the 36-month rule will create more harm than good. The commenter cited an example of an HHA that is poorly run. The HHA, rather than being able to freely sell the business, would now be encouraged to hold on to the HHA until the 36-month clock expires. Another commenter added that even in cases where an HHA owner had every intention of maintaining its ownership for more than 36 months after its initial investment, many personal and professional circumstances can occur to impact that timing.

Response: Given the changes we have adopted in this final rule, we believe that the owner of an HHA as described above would need to make the business decision to remain in the Medicare program or to exit the Medicare program voluntarily.

Comment: Several commenters asked for clarification as to whether indirect ownership changes are subject to the 36-month rule.

Response: Indirect ownership changes are not subject to the 36-month rule. We have clarified this in the regulatory text of the final rule. However, CMS will further analyze and monitor this issue, and may consider modifying this policy in future rulemaking.

Comment: One commenter suggested that indirect ownership changes without significant day-to-day management changes be exempt from the 36-month rule.

Response: As previously stated, indirect ownership changes are not subject to the 36-month rule.

Comment: A commenter stated that with the termination of the provider agreement upon the application of § 424.550(b)(1), Medicare loses the assumption of Medicare liabilities that come with the transfer of the provider agreement.

Response: We appreciate this comment, but believe that the 36-month rule helps us address the program integrity concerns we have outlined.

Comment: One commenter stated that because many states require an HHA to maintain a valid Medicare certification as a condition of Medicaid enrollment, loss of the HHA's enrollment in Medicare could prevent the entity from furnishing Medicaid services.

Response: We understand the commenter's concern. However, we believe that owners of an HHA need to consider the impact of any changes of ownership on all of their payer relationships, not just Medicare.

Comment: One commenter stated that CMS needs to apply caution in detailing regulations that financially impact legitimate HHAs and large numbers of patients. This is especially true if, for instance, a State is involved in purchasing or selling a significant number of HHAs and many CMS–855A applications must be completed.

Response: We agree, and have incorporated public comments into this final rule that protect the Medicare program while helping to ensure that HHAs continue to have access to capital markets.

Comment: One commenter stated that several of CMS's concerns about certificate mills may be somewhat misguided. The commenter cited verbiage in the CY 2010 and 2011 HH PPS rules in which we stated that certain HHA brokers sell the business without having seen a patient or hired an employee. The commenter stated that the entity is required to provide services to at least 10 patients prior to obtaining a provider agreement.

Response: In this final rule, we have incorporated the submission of a full cost report for 2 years as an exception to the 36-month rule. Accordingly, we recognize that some HHAs do not submit cost report data or submit low utilization cost reports.

Comment: One commenter stated that the 36-month rule will be extremely damaging to the home care industry and requested that CMS not implement it.

Response: Though we are unsure as to the commenter's specific concerns about the 36-month rule, we believe, for reasons already stated, that it is necessary.

Comment: Several commenters asked whether § 424.550(b)(1) applies if there is a transfer between partners that changes one person's ownership interest from 40 percent to greater than 50 percent. The commenters questioned the provision's applicability, since the parties have not changed but have simply shifted the assets between them.

Response: Section 424.550(b)(1) applies if there is a change in majority ownership. Since, in the example posed by the commenters, there is a change in majority ownership (that is, a person or entity now owns over 50 percent of the HHA) § 424.550(b)(1) indeed applies, assuming the entity does not qualify for an exception under § 424.550(b)(2).

Comment: One commenter stated that there were two typographical errors in the definition of "majority ownership" in § 424.502. First, the word "months" should immediately follow the phrase "during the 36." Second, after "Medicare program," the phrase "or a change of ownership" should be deleted.

Response: We have revised § 424.502 to incorporate the first change, but we are not incorporating the second change.

(2) Exceptions

Comment: One commenter recommended that if additional assurance is required that an HHA is indeed a viable agency and not being "flipped," we could extend the applicability of the proposed 36-month rule to sales of HHAs that have never filed a full cost report or that have filed a no or low utilization cost report pursuant to the Provider Reimbursement Manual.

Response: We agree in part with this commenter, and have adopted the use of full cost reports in our exception criteria for the 36-month provision and in § 489.28(c)(1). Moreover, we agree that an HHA must submit two or more consecutive full cost reports before the agency can receive an exception under § 424.550(b)(2)(i). It is also important to note that we do not believe the submission of a low utilization cost report or no cost report for a given practice location meets the full cost report standard.

Comment: Several commenters recommended that we adopt a public company exception to the 36-month requirement that states, "A company is acquiring another company that is an HHA (or is the parent company of one or more HHAs) and the majority of the HHAs being acquired are bona fide operating HHAs that have submitted cost reports to Medicare for the previous 36 months or longer."

Response: As already stated, an HHA must submit two or more consecutive full costs reports before it can qualify for an exception under § 424.550(b)(2)(i). We believe this exception would effectively block all unwanted "license flipping" transactions, while ensuring that bona fide operating businesses can obtain financing.

Comment: Several commenters expressed concern over the proposed exception in § 424.550(b)(2)(i) for publicly-traded companies that purchase an HHA. Among the arguments they presented were that: (1) It gives an unfair advantage to publicly-traded firms, (2) it restricts competition and is contrary to the public interest; (3) private companies in many cases have the resources and size comparable to publicly-traded companies; (4) a transaction by a privately-held, bona fide HHA is no less legitimate than one involving a publicly-held company; (5) since the statute does not give publicly-traded HHAs any greater rights or privileges, neither should the 36-month rule; (6) the additional legal and oversight requirements applicable to public companies do not make a difference with respect to compliance with Medicare rules to warrant an exclusive exception; and (7) because most HHAs are small, privately-held companies that lack the resources of some larger, publicly-held companies, the latter have an unfair advantage. Several of these commenters also contended that § 424.550(b)(2)(i) should be expanded to include private companies, and that public and private companies should be exempt if the HHA submitted cost reports to Medicare for the previous 3 years. One commenter stated that this will balance the need to protect the Medicare program without restricting

legitimate transactions. Another commenter, believing that proposed § 424.550(b)(2)(i) is unfair, suggested two additional exceptions. One was for an individual or company that purchases an HHA with an initial investment of $15 million (or some other substantial figure). The second should be for buyers that already operate one or more HHAs with aggregate revenues of greater than $25 million. These prospective buyers, the commenter stated, are not of the types that intend to commit fraud.

Response: Section 424.550(b)(2)(i) has been revised to apply to both private and public companies.

Comment: One commenter stated that the public-company exception should be replaced with an exception for a company acquiring another company that is an HHA (or is the parent company of one or more HHAs), and the majority of the HHAs being acquired are bona fide operating HHAs that have submitted cost reports to Medicare for the previous 36 months or longer. The commenter defined "bona fide" as an operating entity that employs caregivers, provides services to beneficiaries and other patients, and has filed Medicare cost reports for the previous 36 months or longer. Another commenter recommended that CMS exempt from the 36-month rule any "experienced" acquiring party, whether a public or private company. The commenter defined "experienced" as an HHA that has had at least one survey within the last 36 months.

Response: Section 424.550(b)(2)(i) has been expanded to include any HHA that has submitted 2 consecutive years of cost reports (excluding low or no utilization cost reports).

Comment: Several commenters questioned why CMS did not propose an exception for non-profit entities. One commenter requested that CMS furnish a rationale for this decision. Another commenter stated that the transfer of control of non-profit, tax-exempt HHAs to another non-profit, tax-exempt entity should be exempt from the 36-month rule because of other safeguards that prevent "flipping" transactions.

Response: Section 424.550(b)(2)(i) is equally applicable to non-profit and for-profit entities.

Comment: One commenter believed that the exceptions to the 36-month rule were reasonable in view of the need to accommodate legitimate changes in ownership. The commenter added, however, that while non-profits are not engaged in buying and selling HHAs or operating large national chains, non-profits that must merge for financial or other reasons should be offered full support by CMS to ensure the continuation of service to vulnerable patients.

Response: We appreciate the commenter's support for our proposed exceptions to the 36-month rule and, as already mentioned, non-profit entities are included within the purview of § 424.550(b)(2)(i).

Comment: One commenter suggested that any change in ownership of a holding company that owns and operates HHAs through subsidiaries be exempt from the 36-month rule, so long as that holding company has one or more consolidated subsidiaries that have submitted cost reports to Medicare for at least 2 years.

Response: While we appreciate this suggestion, it is moot because, as already mentioned, indirect ownership changes are not impacted by the 36-month rule.

Comment: Several commenters suggested that we establish an exception to § 424.550(b)(1) to permit a qualifying bank or other legitimate lending institution to foreclose on a defaulted loan and to permit the lender to, in turn, sell the HHA to an accredited buyer. Failure to do so will curtail the ability of HHAs to secure financing, since banks will be reluctant to loan money to HHAs if, should the HHA collapse financially, the bank will be unable to foreclose on the business. Another commenter agreed, stating that the proposed 36-month rule eliminates the option of foreclosure as security for lenders.

Response: Since there is no enterprise value to an HHA that is in bankruptcy or where the lender forecloses (except the Medicare billing number), we do not believe that this exception should be adopted in formal rulemaking. However, we believe that we would be compelled to follow a court order approving the sale of an HHA.

Comment: Several commenters suggested an exception for ownership changes triggered by a bankruptcy with court approval. This will allow the HHA to obtain needed capital.

Response: As stated above, we will comply with court orders, but we do not believe that a bankruptcy exception to the 36-month rule is necessary.

Comment: One commenter suggested that we create an exception to § 424.550(b)(1) to allow a buyer that already operates an accredited HHA to acquire an unrelated HHA if the accrediting body extends the buyer's accreditation to include the newly-acquired HHA. Accrediting organizations, the commenter stated, will only extend accreditation if they are satisfied with the buyer's ability to operate the HHA in accordance with its standards.

Response: We appreciate this suggestion. However, we believe that § 424.550(b)(1) and its associated exceptions more adequately provide the program safeguards we desire.

Comment: Several commenters stated that the exception in § 424.550(b)(2)(iv) is superfluous because the death of an owner of 49 percent or less of the business does not result in a change in majority ownership anyway. The commenters suggested that the exception be revised to include the death of a majority owner, provided the remaining owners or partners retain their ownership. One commenter expressed concern that § 424.550(b)(2)(iv) applies only when a deceased owner has less than a 50 percent ownership interest and that the exception applies to all types of business structures. This, the commenter states, could cause the entity undue hardship. Another commenter stated that the transfer of ownership from death should be completely exempt from the 36-month rule, and added that the currently proposed exception does not clarify the types of ownership interests to which it applies.

Response: We have revised § 424.550(b)(2)(iv) to state that the death of an owner does not trigger the 36-month rule.

Comment: A commenter requested clarification of the term "several individuals" as used in proposed § 424.550(b)(2)(iv), which reads: "The death of an owner who owns 49 percent or less interest in an HHA (where several individuals or organizations are co-owners of an HHA and one of the owners dies.)" The commenter asked whether a trust qualifies as an "individual."

Response: The term "several individuals" refers to more than one person, not to trusts. However, the verbiage in parentheses was meant to include all owners regardless of type. It was used only to describe situations in which an HHA has multiple owners. Yet the issue is largely moot based on our aforementioned revisions to § 424.550(b)(2)(iv).

Comment: One commenter asked whether the exception in § 424.550(b)(2)(iv) applies if a corporation owned by three people establishes an HHA under a 49 percent, 49 percent, and 1 percent stock ownership scenario, and one person dies.

Response: As stated above, we have revised § 424.550(b)(2)(iv) to state that the death of an owner does not trigger the 36-month rule.

Comment: Several commenters recommended that CMS reduce the cost reporting time for the proposed exceptions to the 36-month rule from 5 years to 2 years. The commenters believed that 2 years was sufficient.

Response: We agree, and have revised this final rule accordingly.

Comment: Several commenters stated that an ownership change resulting from estate planning should be exempt because it shows a commitment to the delivery of care.

Response: We believe that the expansion of § 424.550(b)(2)(i) will allow a number of bona fide estate transactions to proceed.

Comment: Several commenters stated that the "parent company" exception in § 424.550(b)(2)(ii) should be revised to include the parent's subsidiaries, including the HHA itself. That is, as we understood the comment to read, if the HHA itself is internally restructuring, this should not trigger the 36-month rule, regardless of the number of cost reports the entity has submitted.

Response: We have removed the cost report submission requirement from § 424.550(b)(2)(ii). We note further that § 424.550(b)(2)(iii) exempts certain situations in which the HHA itself is changing its business structure.

Comment: A commenter recommended an exception for changes of ownership involving entities that share a common corporate ownership.

Response: We are not in a position to adopt this suggestion for this particular final rule. Nevertheless, we may consider it as part of a future rulemaking effort.

Comment: One commenter stated that the exception in § 424.550(b)(2)(iii) for a change in business structure should apply if there is no change in the individual owners, regardless of whether there is a change in majority ownership. The commenter further stated that there should be no qualifiers on allowing corporate restructurings where the chain of ownership remains the same. The experience of the HHA—which we interpreted to mean, from the provider's comment, as the filing of cost reports for the previous 5 years—has no bearing on whether the restructuring changes the day-to-day operations.

Response: If the majority ownership is not changing, § 424.550(b)(2)(iii) is inapplicable. However, we have revised § 424.550(b)(2)(iii) to state that a change in business structure—such as a change either to or from a corporation, a partnership (general or limited), or an LLC—does not trigger § 424.550(b)(1) if there is no change in the owners of the HHA.

The cost report submission requirement specified in proposed § 424.550(b)(2)(i) and (ii) was not part of proposed § 424.550(b)(2)(iii), and we have not inserted it into the final version of the latter provision.

Comment: One commenter stated that further clarification is needed related to the internal restructuring that qualifies for the exception.

Response: Though we are uncertain as to type of clarification the commenter seeks, we believe that the exceptions in § 424.550(b)(2)(ii) and (iii) regarding internal restructuring, and the revisions made to the latter, are clear. We note that several examples of the types of restructuring impacted by § 424.550(b)(2)(iii) are included within that provision. CMS, however, may in the future issue further guidance on this subject as needed.

(3) Miscellaneous Program Safeguard Comments

The following is a summary of comments we received on the proposed rule that do not specifically address the merits of our proposed changes to the capitalization provisions and the 36-month rule.

Comment: Several commenters recommended that we provide education to Medicare contractors regarding the implementation of any new provisions related to changes in ownership.

Response: We agree with these commenters, and will develop manual instructions to implement the provisions of this final rule.

Comment: Several commenters stated that this portion of the proposed rule is confusing, contains certain internal language conflicts, and requires clarification. Another commenter stated that further clarification is needed to determine the rule's full impact on HHAs.

Response: Without further information as to the provisions that are of concern to these commenters, we are unable to address these comments.

Comment: One commenter stated that the proliferation of new for-profit HHAs is contributing to the fraud, abuse, and misuse of the HH benefit, and recommended that CMS impose a moratorium on the certification of new HHAs effective immediately. If, the commenter stated, CMS's assertion that there is already adequate access to HH services is true, then adding further capacity creates inefficiency in the system by adding more fixed costs and, in some situations, provider-induced demand.

Response: While we appreciate this comment, it is outside the scope of this final rule.

Comment: Another commenter expressed great concern about the ease of entry into the HH marketplace and raised questions as to the qualifications of certain HHAs that are granted deemed status. The commenter urged CMS to use the final rule to suspend all deemed status certifications and impose a national "cooling off period" for new entries to the marketplace. The commenter suggested that this occur for a minimum of 18 months following publication of this final rule.

Response: While we appreciate this comment, it is outside the scope of this final rule.

Comment: One commenter stated that CMS should ensure that the Medicare contractor completes the processing of tie-in notices within 21 days of its receipt of said notice.

Response: This comment is outside the scope of this final rule.

Comment: One commenter stated that the proposed changes will limit a health system's ability to engage in good business practices.

Response: Without further information as to the specific business practices the commenter refers to, we are unable to address this comment.

4. Provisions of Final Rule

Based on the public comments, we are adopting the provisions of the proposed rule with the following revisions:

- In § 424.502, we have inserted the word "months" immediately after the phrase "during the 36." We have inserted the term "direct" to clarify that the definition of majority ownership only applies to changes in direct ownership of the HHA. We have also changed the verbiage "following the initial enrollment into the Medicare program or a change of ownership" to "following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership," so as to more clearly articulate the definition's applicability.
- In § 424.550(b)(2)(i), we have replaced the "publicly-traded exception" with an exception for an existing HHA that has submitted 2 consecutive years of Medicare full cost reports. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. We have also inserted the phrase "or within 36 months after the HHA's most recent change in majority ownership," to ensure consistency with the verbiage in the definition of "change in majority ownership" in § 424.502.

- In § 424.550(b)(2)(ii), we have eliminated the 5-year period for cost report submissions.
- In § 424.550(b)(2)(iii), a change in majority ownership of the HHA will be exempt from § 424.550(b)(1) if the HHA is changing its existing business structure—such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC—and the owners remain the same.
- In § 424.550(b)(2)(iv), the death of an owner will not trigger § 424.550(b)(1).
- In § 489.28(a), we reemphasized that the HHA must also have available sufficient initial reserve operating funds for the 3 month period following the conveyance of Medicare billing privileges.

F. Home Health Face-to-Face Encounter

As a condition for payment, the Affordable Care Act mandates that, prior to certifying a patient's eligibility for the HH benefit, the physician must document that the physician or a permitted nonphysician practitioner (NPP) has had a face-to-face encounter with the patient. The Affordable Care Act allows the Secretary to determine a reasonable timeframe for the encounter to occur. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs perform the face-to-face encounter. The Affordable Care Act describes NPPs who may perform this face-to-face patient encounter as a nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician.

We proposed a change to the timeframe of the face-to-face encounter. The goal of the Affordable Care Act provision is to achieve greater physician accountability in certifying a patient's eligibility and establishing a patient's plan of care. We believe these goals can be achieved better if the face-to-face encounter occurs closer to the HH start of care, increasing the likelihood that the clinical conditions exhibited by the patient during the encounter are related to the primary reason the patient comes to need HH care. Therefore, we proposed that the encounter occur within the 30 days preceding the start of HH care, if the reason for the encounter is related to primary reason the patient requires home care. If no such encounter occurred prior to the start of HH care, we proposed that the encounter must occur within 2 weeks after the start of care.

Additionally, as part of the Affordable Care Act mandated encounter documentation, we proposed that the physician document on the certification how the clinical findings of the encounter support the eligibility requirements that a patient be homebound and need intermittent skilled nursing or therapy. The Affordable Care Act allows NPPs to perform the face-to-face encounter and inform the certifying physician. We also proposed that a NPP performing the face-to-face encounter with a patient cannot be employed by the HHA providing care, consistent with current policy which precludes a physician who certifies a patient's HH eligibility from having a financial relationship with the HHA.

For a complete description of the Home Health Face-to-Face Encounter proposed implementation approach we refer readers to the CY 2011 HH PPS proposed rule published on July 23, 2010.

Comment: A number of commenters stated concern regarding the feasibility of implementing a face-to-face encounter requirement and they suggested that the face-to-face encounter requirement be removed altogether. Commenters stated opposition to implementation of the face-to-face encounter requirement, fearing that it would cause agencies to go out of business and place stress on the physician-HHA relationship. Another commenter suggested that the face-to-face requirements would also place a strain on the relationship between emergency personnel, such as hospitalists and ER physicians, and primary care physicians. Additionally, some commenters stated that the face-to-face encounters could cause decreased access to physician care services since the physician would be inundated performing face-to-face encounters and would not have enough time to provide medically-related services. Furthermore, a commenter suggested that CMS allow the certifying physician to decide whether or not a face-to-face encounter was even needed. Commenters described the challenges and health risks associated with homebound patients visiting a physician's office for the face-to-face encounter, and some patients would need to be transported via ambulance to see a physician or NPP for the encounter. A few commenters stated that there should be an audit process after HH services are provided as an alternative to implementing face-to-face encounter requirements. Many commenters suggested that the face-to-face encounter requirements would delay and decrease access to HH services, resulting in unnecessary and prolonged visits to hospitals or emergency care settings, which ultimately increase Medicare costs. Commenters also described the burden and additional costs, which agencies will incur as a result of this requirement, with many commenters stating that the requirement will risk access to HH care for Medicare beneficiaries. A commenter asked CMS to explain the rationale behind the requirement for a face-to-face encounter and of HH care. Another commenter asked CMS to clarify whether the face-to-face encounter would be required solely for the first episode or also for consecutive episodes.

Response: We note that section 6407(a) of the Affordable Care Act (as amended by section 10605) amends the requirements for physician certification of HH services by requiring that, prior to making such certification, the physician must document that the physician himself or herself or specified NPP has had a face-to-face encounter with the patient. The legislation mandates the face-to-face encounter as a condition for payment. We are required by law to implement this provision and we do not have the authority to waive the requirement or to adopt alternatives to it. The provision does provide us with some flexibility in the implementation, such as providing us with the discretion to set a reasonable timeframe for this encounter.

While we are sensitive to commenters' concern regarding care risk associated with this requirement, we also note that in enacting this provision, the Congress allowed practitioners other than the certifying physician to perform the encounter. Specifically, the Affordable Care Act describes NPPs who may perform this face-to-face patient encounter as a nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife, as defined in section 1861(gg) of the Act, as authorized by State law, or a physician assistant, as defined in section 1861(aa)(5) of the Act, under the supervision of the physician. The Affordable Care Act also allows the encounter to be satisfied through the use of telehealth services, subject to the requirements in section 1834(m) of the

Act. We remind the commenter that a criterion to be eligible for Medicare's HH benefit has always been that the patient must be under the care of a physician. In response to the commenter who requested that we provide a rationale for the face-to-face encounter, we reiterate that this is a mandate of the Affordable Care Act and, because this is a statutory requirement, we must require this encounter as a condition of payment. However, we believe that more physician and/or practitioner involvement with the HH patient will improve the quality of care provided to the HH patient by providing the physician, who is managing the care plan, with more direct clinical information about the patient which is obtained from the encounter. If a NPP performed the encounter, the NPP would communicate the patient's clinical information obtained during the encounter to the certifying physician. We also believe increased physician involvement will enable the certifying physician to more accurately certify the "homebound" and "in need of skilled services" eligibility requirements, thus promoting more appropriate use of Medicare's HH benefit.

In response to the commenter who asked CMS to clarify whether the encounter is required only for the first episode, we believe that the commenter is asking whether the provision applies to the initial certification or whether it also applies to each subsequent recertification as well. We note that the Congress enacted the requirement to apply to the physician's certification, not the recertification. Therefore, we have interpreted this provision to apply to the initial certification only. In response to the commenter's concern about transporting homebound patients to see a physician in order to meet the requirement, we remind the commenter that we are allowing an encounter which occurred prior to home health admission to satisfy the requirement, with certain caveats, as we describe in more detail in the following response. Also in response to the burden concerns, we refer commenters to a 2001 survey by the OIG which reported that of the physicians in the study sample, 86 percent who sign home health orders see their patients under home health care at least monthly. (*The Physician's Role in Medicare Home Health* (OIG publication No. OEI–02–00–00620)).

Comment: Some commenters expressed concern about the proposed certification timing requirements, stating that the proposed requirements may prevent patients from receiving necessary HH services due to the inability to have a face-to-face encounter in the required timeframe. The time requirement may not be met due to the shortage of certifying physicians and their limited availability and/or the patients' limited transportation options, especially for homebound patients and those who live in rural areas. A commenter also suggested that patients with dementia or behavioral health conditions may have a particularly difficult time meeting the face-to-face requirements. A few commenters described a survey of HHAs which suggested that the proposed timeframe will decrease access to care and cause delays. In order to prevent delays or decreased access to HH care, commenters suggested increasing the timeframe in which a face-to-face encounter must occur. Several commenters believed that if physicians have seen the patient within the last 6 months, then that visit should satisfy the encounter requirement. Some commenters stated that the Congress intended that the face-to-face encounter could occur up to 6 months prior to the initiation of HH services up to and including the date the physician signs the certification. Other commenters suggested other timeframes, such as 90 days prior to the start of care and up to one month after the start of care.

A commenter suggested that CMS start with a long timeframe for the face-to-face encounter requirement and then slowly transition to a shorter timeframe to better address any unforeseen issues and ease the transition associated with this requirement.

One commenter believed there should be stricter requirements for the face-to-face encounter. Two commenters suggested that CMS remove the provision, which allows a face-to-face encounter to be performed after the start of services. One of the two commenters further stated that the reason for the face-to-face encounter requirement is to ensure that the there is an independent evaluation of the need for HH services before they are provided. Allowing services to be provided before this assessment is made may cause confusion if the face-to-face requirements cannot be met, potentially causing a sudden termination of services and a lack of payment for the services already provided. The commenter stated that CMS can prevent these scenarios by requiring that a face-to-face encounter occur before the start of HH services. The commenter also stated that the 30-day timeframe proposed in the face-to-face encounter requirements was appropriate for patients who were discharged from the hospital or emergency room. However, the commenter thought that the 30-day timeframe should be shortened to 15 days for patients who are admitted to the HH setting from the community. The commenters suggested that CMS may want to consider an extended timeframe for the encounter in rural settings. Another commenter believed that the face-to-face requirements be altered or completely removed in rural areas.

Other commenters urged CMS to abandon the proposed requirement which states that the encounter must be related to the reason the patient needs home care, describing concerns with enforcement of such a provision. Commenters have suggested that when a patient's condition changes, communication between the certifying physician and the HHA is sufficient and can replace the need for a more current face-to-face encounter.

A commenter asked CMS how it would ensure that there was, in fact, a face-to-face encounter within the timeframe.

Other commenters stated that there may be scenarios where patients are seen by specialists who do not act as their certifying physician. In this case, a primary care physician would need to perform a face-to-face encounter; however, the encounter could be redundant since the patient was already seen by the specialist. Similarly, another commenter stated that often patients will be referred to HH services by resident physicians or hospitalists and they may not be able to see a primary care physician for the face-to-face encounter. In addition, while the patient is in the hospital or emergency care setting, the primary care physician may not have hospital privileges and may not be allowed to see the patient. Furthermore, commenters have stated that even if hospitalists and emergency room physicians are allowed to certify the face-to-face encounter, they may be hesitant to do so since they would not want to or be able to take over the plan of care responsibilities. A commenter suggested that the primary care physicians be allowed to certify HH services after reading the hospitalist's discharge summary. Also, a commenter stated that there already are problems with delays in starting HH services due to patients' lack of follow-up visits or infrequent visits with their primary care physician. Other commenters have stated that some patients do not have a primary care physician and may need to be treated by a community-based or clinic physician, which may take longer than 14 days to have the face-to-face encounter. Moreover, commenters expressed concern with a timeframe of 2 weeks after the start of care to have the

face-to-face encounter, stating that, should a timely encounter not occur, the HHA would then lose money for services provided during that time and the patient would not receive all of the necessary services. The HHA would be held financially liable when the patients or physicians are at fault. A few commenters asked whether an agency could require patients to sign an Advanced Beneficiary Notification (ABN), which would allow the agency to hold the patient financially responsible if a face-to-face encounter did not occur as required. Commenters expressed concerns where a patient might not be able to secure an appointment or obtain transportation within the 2-week timeframe or who may be physically unable to get to the doctor's office. Another commenter suggested that there be an exception provision to the timeframe requirements if there was sufficient documentation that showed that there was a reasonable attempt to schedule a face-to-face encounter with a physician. A commenter also asked CMS to clarify whether partial payment would apply if the encounter occurred, but did not occur during the required timeframe.

Some commenters thought that a hospitalist's or specialist's face-to-face encounter could serve as the certifying encounter. Other commenters also thought that the hospitalist or specialist could sign the plan of care. Additionally, commenters suggested that the physician who has the best understanding of the patient's condition should serve as the certifying physician and a primary care physician can then formulate and sign the plan of care and take over responsibility for further care. Alternatively, a commenter proposed that the "HHA medical director" be allowed to act as the certifying physician in the face-to-face encounter or the HHAs hire physicians to perform the face-to-face encounter. Another commenter asked if and how a part-time HHA medical director could serve as a primary care certifying physician.

Furthermore, a commenter suggested that a HHA employee find out the patient's last face-to-face physician encounter and document the date. If the date was within 6 months of the HH referral, then the patient could receive HH services. If the patient had not seen a physician in 6 months, the commenter proposed that the patient see a physician before he or she could be enrolled in HH care services. The commenter also recommended that the date of the face-to-face encounter be placed on the plan of care.

A commenter also thought that the same timing standards currently used for certification be applied to the face-to-face encounter certification.

Response: In the proposed rule, we proposed that the encounter occur within the 30 days preceding the start of HH care, if the reason for the encounter is related to the primary reason the patient requires home care. If no such encounter occurred prior to the start of HH care, we proposed that the encounter must occur within 2 weeks after the start of care. We believe that this timeframe increases the likelihood that the clinical conditions exhibited by the patient during the encounter are related to the primary reason the patient comes to need HH care. We also believe that this timeframe best meets the program integrity and quality goals associated with the provision. The timeframe ensures that the certifying physician can accurately determine whether the patient meets the homebound and skilled need eligibility criteria while also ensuring that the physician understands the current clinical needs of the patient to establish an effective care plan. Additionally, a recent study shows that physician involvement with the HH patient within 30 days prior to HH admission results in significantly better patient outcomes. Patients receiving a face-to-face physician visit within 30 days of HH care were 1.45 times more likely to be discharged without hospitalization than patients who did not receive a face-to-face physician visit during their episode of care (Wolff et al., 2009, p. 1151 [1]). We incorporated studies such as this one and our clinical judgment in the creation and formation of the proposed timeframe. However, we found some of the commenters' concerns compelling. Regarding the feasibility of the proposed timeframes and the corresponding access to care risks, especially in rural areas, we will revise the timeframes described in the proposed rule to allow the encounter to occur up to 90 days prior to the start of care, if the reason for the encounter is related to the reason the patient comes to need HH care. If no such encounter has occurred, we will allow the encounter to occur up to 30 days after the start of care. This alternative timeframe was recommended in comments submitted by a major association of home care physicians. The comments described that chronic illnesses among the elderly are commonly associated with an office visit every 3 months, and by adopting a timeframe where the encounter could occur up to 3 months prior to the start of care, we would significantly mitigate the access to care risk. For those patients who had no encounter during the 3 months prior to the start of care which was related to the reason the patient comes to need HH care, we will allow the encounter to occur up to 30 days after the start of care. We continue to believe that it is essential for the encounter to be related to the reason the patient comes to need home care. Otherwise, the encounter does not meet what we believe to be the goals of the provision—to enable more appropriate use of the benefit while also improving the physician's ability to manage the patient's care. However, we understand the commenters' concerns surrounding enforcement of this provision. It is not our intent that those who enforce the provision would take such a literal interpretation to look for a cause and effect relationship between a diagnosis on the physician's claim and the diagnosis on the HH claim. Instead, it is our intent that should a patient's clinical condition change significantly between the time of the encounter and the start of home health care such that the physician's or NPP's ability to accurately assess eligibility and care plan would be at risk, a more current encounter would be necessary in order to meet the goals of the statutory requirement. As such, to address the commenters' concerns, we will expand on this requirement in manual guidance which we believe is the appropriate venue for such clarification.

We disagree with the commenters who stated that the Congress intended for us to allow the face-to-face encounter timeframe to encompass the 6 months prior to the date on which the physician signs the certification. If this was the Congress's intent, the legislative provision would not have included specific language, "reasonable timeframe as determined by the Secretary," which allows the Secretary to determine the timeframe.

We disagree with the commenter who suggested that the encounter must occur prior to the start of care. We believe that it will not be uncommon that a patient needs home care but has not seen a physician in the 3 months prior to the start of care and this should not preclude access. As is the practice today, the HHA would be responsible for ensuring that services are provided to eligible patients, and the face-to-face encounter, associated documentation, and signing of the certification would occur after the start of care.

In response to the commenters who believe that we should abandon the proposed criterion that the encounter

[1] Wolff, J. L., Meadow, A., Boyd, C. M., Weiss, C. O., & Leff, B. (2009). Physician evaluation and management of Medicare home health patients. *Medical Care. 47*(11), 1147–1155.

has to be related to the reason the patient has come to need HH, we continue to believe that in order to achieve what we believe to be the goals of the provision, the encounter must occur close enough to the HH start of care to ensure that the clinical conditions exhibited by the patient during the encounter are related to the primary reason for the patient's need for HH care. It ensures that the certifying physician can accurately determine whether the patient meets the homebound and skilled need eligibility criteria while also ensuring that the physician understands the current clinical needs of the patient to establish an effective care plan.

In response to the commenter who wanted to know how we would ensure that there was, in fact, a face-to-face encounter within the timeframe, we will issue instructions to the contractors who perform medical reviews to ensure compliance with this regulation. We also expect that other program integrity oversight efforts will be effective vehicles to monitor compliance with this condition of payment. We also expect that surveyors will monitor compliance with this requirement. In response to the commenter who asked that we clarify whether partial payment would apply if the encounter occurred outside the required timeframe, we reply that the Affordable Care Act established this provision as a condition of payment and therefore we would have no statutory authority to partially pay an agency if they complied with some but not all of the provision.

To address the commenters' concerns surrounding which physician must perform the face-to-face encounter and document that the face-to-face encounter occurred, we remind the commenter that the Affordable Care Act requires the certifying physician to document that the physician himself or herself or specified NPP has had a face-to-face encounter (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act) with the patient. The Affordable Care Act describes NPPs who may perform this face-to-face patient encounter as a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician, in accordance with State law, a certified nurse-midwife (as defined in section 1861(gg)of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5)of the Act), under the supervision of the physician.

Where the patient is admitted to HH from the hospital, we believe that current practice associated with the HH certification would apply to the face-to-face encounter as well. In most cases, we would expect the same physician to refer the patient to HH, order the HH services, certify the beneficiary's eligibility to receive Medicare HH services, and sign the plan of care. It would be this physician who would be responsible for documenting on the certification that he or she, or a specified NPP working in collaboration with the certifying physician, had a face-to-face encounter with the patient. However, we recognize that, in certain scenarios, one physician performing all of these functions may not always be feasible. An example of such a scenario would be a patient who is admitted to HH upon hospital discharge. While we would still expect that in most cases, a patient's primary care physician would be the physician who refers and orders HH services, documents the face-to-face encounter, certifies eligibility, and signs the plan of care, there are valid circumstances when this is not feasible for the post-acute patient. For example, as several commenters pointed out, some post-acute HH patients have no primary care physician. In other cases, the hospital physician assumes primary responsibility for the patient's care during the acute stay, and may (or may not) follow the patient for a period of time post-acute. In circumstances such as these, it is not uncommon practice for the hospital physician to refer a patient to HH, initiate orders and a plan of care, and certify the patient's eligibility for HH services. In the patient's hospital discharge plan, we would expect the hospital physician to describe the community physician who would be assuming primary care responsibility for the patient upon discharge. It would be appropriate for the physician who assumes responsibility for the patient post-acute to sign the plan of care and thus be considered "under the care" of that community/personal physician throughout the time the patient is receiving HH services. In a scenario such as this, if the hospital physician certifies the patient's HH eligibility and initiates the orders for services, the hospital physician could document that a face-to-face encounter occurred and how the findings of that encounter, which in this scenario would have occurred during the patient's acute stay, support HH eligibility. The community physician designated on the discharge plan would assume responsibility for the patient at some point after acute discharge, updating orders, signing the plan of care, etc.

It is important to reiterate that to be eligible for Medicare's HH benefit, the patient must be under the care of a physician, and it is ultimately the responsibility of the HHA that this criterion is met. We have always held the HHA responsible for ensuring that there is a physician-signed plan of care, physician-signed orders, and a physician-signed certification. Therefore, we will also hold the agencies responsible for the certifying physician's encounter documentation. By statute, this documentation is a requirement for payment just as a physician-signed certification of eligibility is a requirement for payment. As such, the requirements for the face-to-face encounter documentation have many similarities to the existing certification requirements. We have no flexibility to adopt exceptions to the statutory face-to-face documentation requirements.

In response to the commenters who suggested that they deliver an HHABN to the HH patient describing the patient's possible financial liability should the face-to-face encounter not occur as required, this practice is not permitted. The HHABN, Form CMS–R–296, has been approved by the Office of Management and Budget (OMB) to provide limitation of liability protections to Original Medicare beneficiaries receiving HH services under section 1862(a)(1)(A)of the Act for care that CMS or its contractors determines is not reasonable and necessary under Medicare; section 1862(a)(9) for custodial care; (g)(1)(A) for care when the beneficiary is not homebound; and section 1862(g)(1)(B) for care provided to a beneficiary who is not in need of skilled nursing care. The HHABN must not be used to transfer liability to the beneficiary when technical requirements for payment, such as a face-to-face encounter, are not met. The HHABN is not approved for this use.

In response to the commenters who requested that HHA medical directors act as the certifying physician in the face-to-face encounter or that the HHAs hire physicians to perform the face-to-face encounter, we remind the commenters of longstanding regulatory prohibitions in § 424.22 which impose financial restrictions on the relationship between the HHA and the certifying physician. We continue to believe that these financial restrictions strengthen the integrity of the benefit.

Comment: Commenters have also expressed concern about the requirement that the face-to-face encounter be related to the reason the patient needs HH services and concern

about the documentation and rationalization requirements. Commenters also stated that the HHA has no control over the quality of the physician's documentation and no method to enforce proper physician documentation. A commenter suggested that the increased documentation responsibilities placed on the primary care physician would result in fewer referrals to HH. The commenter also stated that since the HHAs have no control over the quality of a physician's documentation, there should be a "without fault" provision applied when there is proper certification but lack of proper documentation. Furthermore, another commenter stated that it will be extremely costly for agencies to change their documentation systems to ensure the face-to-face encounter documentation is sufficient. Moreover, the commenter stated that there should be payment guarantees so that HHAs are not penalized because of improper physician documentation. A commenter suggested that CMS not finalize the proposed requirement that the physician's own medical record documentation be consistent with the encounter documentation on the certification. Another commenter suggested that CMS should not withhold payment for failing to meet the encounter documentation and instead impose other sanctions. One commenter also suggested that CMS provide payment even when a face-to-face encounter does not occur if the HHA can show that it informed patients and physicians of the requirements. In addition, a commenter suggested that agencies be protected from potential patient complaints that may be a by-product of these requirements. Another commenter suggested that CMS should not withhold payment for failing to meet the encounter documentation and instead impose other sanctions. Some commenters have suggested a gradual implementation of the new face-to-face requirements, or delaying the implementation of the new face-to-face encounter requirements. Commenters stated that the face-to-face encounter documentation requirements will slow the HHAs' efforts to move to electronic health records. Commenters have also stated that there are language barriers with communicating the new face-to-face encounter requirements. Other commenters requested that CMS permit HHAs to include standardized language on the certification form which would be signed and dated by the certifying physician to suffice as the encounter documentation. Commenters asked CMS to educate physicians and beneficiaries about the new face-to-face requirements, the rationale for the requirements, and their responsibility in these requirements.

Response: We thank the commenters for their suggestions. Regarding the comment, which suggested that we permit HHAs to include standardized face-to-face encounter language on the certification form, which would be signed and dated by the certifying physician, we remind the commenter that the statutory language in the Affordable Care Act requires that prior to certifying, the physician must document that the face-to-face encounter occurred. The law requires this as a condition for HH payment. We proposed that the documentation of the encounter be a separate and distinct section of, or an addendum to, the certification, and that the documentation include why the clinical findings of the encounter support HH eligibility. We believe that our proposed documentation requirements meet the Congress' intent for more physician involvement in determining the patient's eligibility and managing the care plan. We believe that were we to allow the HHA to craft standard language which the physician would then simply sign, we would not achieve the sort of physician involvement in the eligibility determination and care plan which was the Congress' intent. As such, we believe that if a HHA were to develop standardized encounter language to be signed by the physician, they would not be adhering to the statutory payment requirements that the "physician document" the encounter. Similarly, regarding the comment that we should not withhold payment, or should consider imposing other non-payment sanctions, or hold the HHA "without fault" for failing to meet the encounter documentation requirement, we reiterate that the law requires the physician to document that the face-to-face encounter occurred prior to certifying HH eligibility, as a condition of payment. Under section 6407(b) of the Affordable Care Act, we have no legal authority to exempt a HHA from this requirement, or to impose alternate sanctions if a HHA fails to meet a statutory payment condition.

Regarding the commenter who requested that we should not require the physician's own medical record documentation to be consistent with the documentation on the certification, we understand the commenter's concern, and we will revise the proposed regulation text to make clear that we are not holding the HHA responsible for the physician's own medical record documentation associated with the encounter. We would expect that a physician who performs a medically necessary physician service, which also satisfies the face-to-face encounter requirement, would maintain medical record documentation concerning the encounter, and the clinical findings associated with that encounter would be consistent with the physician's certification documentation. However, it is not our intent to penalize the HHA if the physician's own medical record documentation associated with the encounter is not in good order. Rather, we would look to the physician to fulfill his or her responsibility for ensuring appropriate medical record documentation associated with the encounter, and any associated Medicare billing. Regarding the commenter who asked us to protect agencies from complaints, which may be associated with this provision, we are unsure what the commenter means. We will continue to require providers to adhere to quality care practices while adhering to Medicare's Conditions of Participation.

We concur with the commenter who suggests that we educate physicians regarding this new law, and will do so via open door forums, listserv announcements, and MedLearn articles.

Regarding the comments which requested that we delay the face-to-face requirements, the comment that the face-to-face encounter documentation requirements will slow the HHAs' efforts to move to electronic health records, and the comments that suggested there are language barriers with communicating the new face-to-face encounter requirement, we again reiterate that this is a statutory requirement, which we must implement. We do not understand the rationale behind the commenter's fear that this requirement would delay adoption of electronic health records. We suspect this commenter is concerned that agency resources which might have been directed toward adopting electronic health records would be re-directed to implement this provision. We again reiterate that this is a statutory requirement, which we are required to implement.

We are also confused why the commenter believes that language barriers would preclude the face-to-face encounter, and remind the commenter that being under the care of a physician is a longstanding eligibility requirement for the HH benefit.

Comment: Commenters stated concern regarding the requirements for a face-to-face encounter by telehealth, stating that the current qualifications for telehealth coverage should not apply to the face-to-face encounter by telehealth

and that CMS has overly strict requirements on the parameters for a face-to-face encounter by telehealth. The current qualifications require the patient to go to an "originating site" outside of their home; however, by doing so, the patient's homebound status and therefore eligibility for HH services may be questioned. The commenter requested that CMS use section 1834(m) of the Act solely to define telehealth and expand the definition of telehealth services to allow for the use of equipment in the patient's home. Some commenters suggested that the face-to-face encounter by telehealth can be satisfied via telephone calls from the physician to the patient. Other comments suggested that CMS allow face-to-face telehealth visits at the patient's home and that the use of technology, such as video chat and remote assessment devices, be allowed in the telehealth visits.

Response: There are several codes that are currently defined as Medicare telehealth services that could be used to furnish and bill for medically necessary physician services, which would satisfy the encounter requirement, if furnished by telehealth. However, section 1834(m) requires the patient to be located at one of several specified types of originating sites, and we have no flexibility to permit telehealth services to be furnished to a patient in the home.

Regarding the comment that a patient's visit to a physician's office or telehealth originating site would threaten the patient's homebound status, we note that longstanding policy describes that if a patient leaves the home for health care treatment, the patient would nevertheless be considered homebound.

Comment: Several commenters stated concern regarding the proposed restriction that NPPs who are employed by the HHA cannot perform the face-to-face encounter. Commenters state that the proposed regulation imposes stricter financial criteria on the relationship between the HHA and NPPs who are performing the face-to-face encounter than has previously been applied to physicians who certify HH eligibility. Commenters stated that by having the same financial relationship criteria for certifying physicians and NPPs performing a face-to-face encounter, CMS will minimize conflict of interest while maximizing the number of medical personnel who are qualified to perform the face-to-face encounter. Other commenters believe that HHA NPPs should be allowed to perform the face-to-face encounter, noting that the increase in integrated health systems and associated efficiencies in providing care would justify allowing the practitioner to be an employee of the HHA. Several commenters also requested that NPPs be allowed to certify HH eligibility.

Response: We believe that given the HH program integrity concerns in certain pockets of the country surrounding the certification of HH eligibility, it is imperative that NPPs be subject to the same financial limitations with the HHA as currently apply to the certifying physician. We agree with the commenters that the NPPs should not be subject to harsher financial limitations with the HHA than the certifying physician and we have revised the proposed § 424.22 accordingly. In response to the commenter who requested that NPPs be allowed to certify HH eligibility, we remind the commenter that sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act prohibit this.

Comment: Commenters expressed concern about the requirements for a physician signature and date on the encounter certification, stating that often physicians will not date documents. Commenters stated opposition to the requirement for a date from the physician, stating that this requirement would cause unnecessary burdens as the agency could frequently be resending certifications back to physicians to obtain the date. Commenters stated that since CMS has previously allowed the agency to date the certification based on the receipt date for other documents, CMS should apply the same policy to the encounter certification date. One commenter explicitly stated that the receipt date is adequate proof that the agency received the required documentation before billing for the HH services.

Response: The requirement that a physician date the certification reflects longstanding manual guidance. As such, this is existing policy. We are taking this opportunity to codify this in regulation for clarification.

Comment: Some commenters suggested that CMS increase the reimbursement associated with the current billing code (G0180) which physicians use when billing for their services associated with Medicare HH certification. Other commenters questioned whether the face-to-face encounter visits would be separately reimbursed by Medicare. Commenters wanted CMS to clarify whether the certification will be billed separately from the face-to-face encounter. Furthermore, the commenters wondered what the pay codes would be for the face-to-face encounter and suggested that there would be delayed RAP payment to agencies since agencies would need to wait until the proper certification and documentation were collected in order to receive payment. Another point commenters brought up was that residents may have more than one residence and therefore they may need more than one certifying physician, further burdening patients who require HH services. Also, commenters stated that by requiring the face-to-face encounter, the patient must pay an additional twenty percent copayment for the physician visit, which may be costly, particularly for those patients who were recently discharged from the hospital and were required to pay their Medicare hospital deductible as well. Commenters brought up the example that a patient may not want to have a face-to-face encounter with a physician when there is no medical reason for the visit. Moreover, a commenter proposed that CMS continue to pay RAPs through its current method; however, CMS should change the payment of the final claims based on the signed certification.

Response: It is our intention to allow RAP payments as we currently do today while the HHA is awaiting physician completion of the certification. If the face-to-face encounter included medically-necessary covered physician services to the HH patient, the physician could bill Medicare for these covered services under the physician fee schedule. Regarding the physician billing practices associated G0180, we see no need to change those requirements or the associated reimbursement. Regarding the post acute patient co-pay concern, we refer the commenter to the response to the comment above which describes the role of the hospitalist in the face-to-face encounter. Regarding the broader copayment comment, we again remind the commenter that a HH patient must be under the care of a physician as an eligibility requirement, and therefore would expect that regular physician visits to occur during the HH course of treatment. As such, we do not believe that a face-to-face encounter would impose a new copayment financial burden on the patient.

Comment: Some commenters were supportive of our proposal to allow NPPs to have the face-to-face encounter. Commenters also agreed that employees of the HHA should not be allowed to do the face-to-face encounter. The commenters also agreed with the face-to-face encounter requirements and the documentation requirements and that the encounter requirements should be able to be fulfilled through the use of telehealth.

Response: We thank the commenters for their support.

Comment: Some commenters expressed concern that the face-to-face encounter requirement would bring into question a patient's right to refuse a clinical visit for care that is for regulatory compliance only and not medically necessary.

Response: We again remind the commenters that this is a mandate of the Affordable Care Act and, because this is a statutory requirement, we must require this encounter as a condition of payment. We would expect that practitioners would typically be conducting a medically necessary service to the patient, and this service would also meet the face-to-face encounter requirement. We disagree with the commenters that such encounters satisfy a regulatory requirement only. We refer again to the research,[2] which shows that physician visits result in better HH patient outcomes. Finally, we also remind the commenters that, in order to be eligible for the Medicare HH benefit, a patient must be under the care of a physician. Should a patient refuse to have a face-to-face encounter with the physician responsible for care, CMS would question whether the patient was legitimately under the care of the physician.

We thank the commenters for their insightful comments. In summary, we will finalize the proposed implementation approach with the following exceptions:

We will revise the timeframes described in the proposed rule to allow the encounter to occur up to 90 days prior to the start of care, if the reason for the encounter is related to the reason the patient comes to need home health care. If no such encounter has occurred, we will allow the encounter to occur up to 30 days after the start of care. We will also revise the proposed regulation to re move the requirements concerning the physician's own medical record documentation. We will also revise the regulation text to impose the same financial restrictions with the HHA to nonphysician practitioners who perform the face-to-face encounter as currently apply to certifying physicians.

G. Future Plans to Group HH PPS Claims Centrally During Claims Processing

Generally speaking, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for case-mix and geographic wage variations. The national standardized 60-day episode payment rate includes services from the six HH disciplines (skilled nursing, HH aide, physical therapy, speech language pathology, occupational therapy, and medical social services) and nonroutine medical supplies. Durable medical equipment covered under HH is paid for outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the Outcome & Assessment Information Set (OASIS) instrument. On Medicare claims, the HHRGs are represented as Health Insurance Prospective Payment System (HIPPS) codes.

At a patient's start of care, at the start of each subsequent 60 day episode, and when a patient's condition changes significantly, the HHA is required to perform a comprehensive clinical assessment of the patient and complete the OASIS assessment instrument. The OASIS instrument collects data concerning 3 dimensions of the patient's condition: (1) Clinical severity (orthopedic, neurological or diabetic conditions, etc.); (2) Functional status (comprised of 6 activities of daily living {ADL}); and (3) Service utilization (therapy visits provided during episode). HHAs enter data collected from their patients' OASIS assessments into a data collection software tool. For Medicare patients, the data collection software invokes HH PPS Grouper software to assign a HIPPS code to the patient's OASIS assessment. The HHA includes the assigned HIPPS code on the Medicare HH PPS bill, ultimately enabling our claims processing system to reimburse the HHA for services provided to patients receiving Medicare's HH benefit.

Additionally, the HHA is separately required to electronically submit OASIS assessments for their Medicare and Medicaid patients to CMS via their state agency. On the HH PPS Web site at *http://www.cms.gov/homehealthpps/01_overview.asp,* we provide a free OASIS assessment data collection tool (HAVEN) which includes the HH PPS grouper software, a separate HH PPS grouper program which can be incorporated into an HHA's own data collection software, and HH PPS data specifications for use by HHAs or software vendors desiring to build their own HH PPS grouper. Most HHAs do not use the HAVEN freeware, instead preferring to employ software vendors to create and maintain a customized assessment data collection tool which can be integrated into the HHA's billing software. Likewise, many vendors employed by HHAs do not utilize the HH PPS grouper freeware, instead preferring to build their own HH PPS grouper from the data specifications which we provide.

In 2008, we deployed the first refinements to the HH PPS since its inception in 2000. Prior to the 2008 refinements, we made infrequent, minor changes to the HH PPS grouper software. Effective with the refinements, the HH PPS grouper became more complex and more sensitive to the yearly ICD–9–CM code changes. As a result, since 2008, HHAs have been required to update their HH PPS grouper software at least once each year. Most HHAs employ software vendors to effectuate these updates. HHAs have expressed concerns to CMS that the frequent grouper updates coupled with the additional complexity of the grouper has resulted in unexpected costs and an increased burden to them.

In addition, since the 2008 refinements were implemented, we have identified a significant increase in OASIS assessments submitted with erroneous HIPPS codes. These errors occur when HHAs or their software vendors inaccurately replicate the HH PPS grouper algorithm into the HHA's customized software. The significant increase in these errors since 2008 suggests that many HHA software vendors are struggling to accurately replicate the complex algorithms in the HH PPS grouper. We inform HHAs if the submitted HIPPS on the OASIS is inaccurate and provides HHAs with the correct HIPPS to enable the HHA to accurately bill Medicare. However, HHAs have expressed concerns that the HH PPS grouper complexities increase their vulnerability to submit an inaccurate HIPPS code on the Medicare bill. Further, some HHAs have expressed concern that this vulnerability will further increase when the U.S. health care industry permanently transitions from ICD–9 to ICD–10 for medical diagnosis and procedure coding in October 2013, because the ICD–10–CM migration will require major changes to an already complex HH PPS grouper.

Because of these concerns, we have begun analyzing options to streamline the process which assigns HIPPS codes. We are analyzing an option, which would enable us to assign HIPPS codes to the HH PPS bills during claims processing. If we are successful in

[2] Wolff, J.L., Meadow, A., Boyd, C.M., Weiss, C.O., & Leff, B. (2009). Physician evaluation and management of Medicare home health patients. *Medical Care. 47* (11), 1147–1155.

implementing this option, OASIS assessment data collection tools would no longer invoke HH PPS grouper software to assign HIPPS codes to the OASIS assessments. Further, HHAs would no longer be required to include HIPPS codes on HH PPS bills. Such a process would relieve the HHA of all responsibility associated with the HH PPS grouper. If we can centralize the assignment of the HIPPS code to the HH PPS bill during claims processing, we will achieve process efficiencies, improve payment accuracy by improving the accuracy for HIPPS codes on bills, decrease costs, and burden to HHAs, and better position HHAs and CMS for an easier transition from ICD–9 to ICD–10 codes in the future.

Several changes have occurred recently that allow CMS to consider this option of assigning HIPPS codes to the HH PPS bills during claims processing. National claims coding standards have expanded the number of positions of data available in the treatment authorization field on the bill from 18 to 30. In addition, the National Uniform Billing Committee has created occurrence code 50 for assessment reference dates. This new code 50 will allow a separate field for HHAs to report the M0090 assessment date currently carried in the treatment authorization field. These two changes provide enough space on the HH PPS bill for HHAs to encode all the OASIS payment items on the bill, thus potentially enabling the HIPPS code to be computed during claims processing.

However, a major challenge exists with the feasibility of computing the HH PPS group during claims processing is the awarding of case-mix points for reported primary and secondary diagnoses. A centralized HH PPS grouper would look to the diagnoses on the HH PPS bill for grouping. The Health Insurance Portability and Accountability Act (HIPAA) authorized CMS to require that all diagnoses on the bill comply with ICD–9–CM coding guidelines as set out at 45 CFR 162.1002 (65 FR 50370, August 17, 2000). Currently, when certain conditions apply, to prevent the loss of case-mix points, the HH PPS grouper will award case-mix points to some diagnoses reported as a secondary diagnosis when the assignment is performed to comply with ICD–9–CM coding requirements. We currently instruct HHAs to report these diagnoses in M1024 (previously M0246) on the OASIS to prevent loss of case-mix points.

We provide detailed guidance on this topic in page 5 of Appendix D within the OASIS Implementation Manual, which can be accessed at *http://www.cms.gov/HomeHealthQualityInits/downloads/HHQIAttachmentD.pdf.* This coding guidance has been provided to prevent the loss of case-mix points when an underlying case-mix diagnosis is associated with the primary V-code diagnosis.

As required by 45 CFR 162.1002, those diagnoses currently encoded in M1024 (formerly M0246) which should not be reported as primary or secondary diagnoses cannot be reported on the bill. In an attempt to solve this problem, we are analyzing options to map diagnoses currently reported in M1024 (formerly M0246) to diagnoses that are reportable as primary and secondary diagnoses in the HH setting, per ICD–9–CM coding guidelines. We have been encouraged with our ability to map some trauma codes reported in M1024 to after-care codes, which are reportable as primary and secondary diagnoses in the HH setting. However, additional analysis and mapping are needed to fully resolve this challenge.

We solicited public comments on the potential enhancement described above to assign the HIPPS code to the HH PPS bill during claim processing. This enhancement would require HHAs to report all the OASIS items necessary to group the episode on the HH PPS bill. As stated above, reporting on OASIS items on the bill would address the costs and burden HHAs currently experience with regards to frequent updates of a complex HH PPS grouper, address vulnerabilities that HHAs have associated with the possible submission of inaccurate HIPPS codes on the claim, while better positioning HHAs and CMS for the ICD–9 to ICD–10 transition. We are in the early stages of assessing the feasibility of such changes, and wanted to seize the opportunity to solicit the public for their comments on this topic.

The following is summary of the comments we received regarding the proposal to group HH PPS claims centrally.

Comment: Several commenters stated their support of our proposal to centralize grouping of HH PPS claims as long as the HH grouper continued to remain available for HHAs and their vendors.

Response: We recognize that HHAs and their vendors will continue to have a need for the HH grouper software. Therefore, we do not have any plans to discontinue this process should we decide to implement the grouping of HH PPS claims during claims processing.

Comment: One commenter suggested that we anticipate and plan to develop the appropriate claim response for claims that contain data errors that prevent the calculation of a HIPPS code.

Response: We appreciate this feedback and will be sure to address this concern should we decide to move forward with this proposal. We will note that currently our claims processing system has specifications that define valid values for each field. The necessary guidance would be provided to HHAs and their vendors for implementation of this requirement.

Comment: One commenter stated that our proposal does not specify the effect of this proposed change on the current Resident Assessment Protocol (RAP) and final claim processing timelines.

Response: The proposal to group HH PPS claims centrally during claims processing has no effect on the RAP or final claims processing timelines. In fact, the RAP is not utilized in the HH setting. In terms of the final claims processing timelines, the long standing guidelines for our contractors will continue to apply. The guidance can be accessed at *http://www.cms.gov/manuals/downloads/clm104c01.pdf* through the Internet only manual, IOM 100–4 Chapter 1 Section 80.2.1.

Comment: Several commenters stated that while we identified a concern regarding the increased number of errors in HIPPS codes submitted, we did not acknowledge errors identified by HHAs and their vendors in the HHRG released by us.

Response: Beginning in 2010, we put into place a mechanism for our contractor that developed the HHRG software for CMS to beta test any updates to the software with interested parties. All issues noted during beta testing are to be addressed by our contractor prior to final release of an updated HHRG. Our aim is to permit proper vetting of any grouper such that we can avoid errors within our HHRG in the future.

Comment: One commenter stated that grouping HH PPS claims centrally during claims processing does not reduce burden upon HHAs because the burden of reporting HIPPS codes is replaced with one of reporting OASIS items.

Response: OASIS information reported on claims under this proposal would be reported in claims fields currently used by HHAs; so we do not believe that requiring a replacement of data in current fields represents an additional burden.

Comment: Several commenters stated that our solicitation of comments did not provide enough detail surrounding the impact upon accounts receivable information to provide meaningful comments. The commenters suggested a separate **Federal Register** notice be issued.

Response: We appreciate this feedback and believe that based upon our plans to continue to provide the HHRG software, that the concern about potential impact upon HHA operations and their accounting needs will be addressed. In addition, should we decide to implement this provision in a future regulation, we will address additional details through a notice of proposed rulemaking in which additional comments can be provided by HHAs.

Comment: One commenter stated concern that our future plans to group HH PPS claims centrally during claims processing will create a burden on HHAs and their vendors.

Response: We appreciate this feedback and believe that since the data being reported duplicates the information necessary for OASIS, we are not creating additional burden for HHAs and their vendors. In addition, as noted above, the proposed reporting of this information would replace other data in currently used claims fields.

Comment: Several commenters stated that there are no details surrounding how the grouper assignment would be communicated back to the agencies and on claims.

Response: The HIPPS code that our claim processing system assigns will be added to the claim record so that the provider will be able to view the assignment upon online look-up. The HIPPS code assigned will also be returned on the electronic remittance advice.

Comment: A commenter asked about OASIS data corrections identified after the claim is submitted and how the corrections process will be handled and its effect on payment. In addition, the commenter would like to know whether HIPPS code will be assigned at the RAP or on the final claim.

Response: The HIPPS code would be assigned on both the RAP and the final claim. If OASIS data corrections caused the HIPPS code assigned to the episode to change, the HHA would be able to cancel and resubmit the RAP for the episode. This resubmission process to the RAP presently occurs. HHAs that do not maintain grouping software for their internal purposes would have access to the HIPPS code calculated by the State OASIS system.

Comment: A commenter asked how Medicare Advantage (PFFS) payors will be able to calculate the HHRG in the future based upon implementation of this proposal. In addition, the commenter stated concerns that if the HHRG software is not made available that the HHAs will be unable to advise patients of the copayment amounts.

Response: We appreciate this feedback and again want to reassure HHAs and their vendors that we plan to continue to make the HHRG software updates available for use which will permit the Medicare Advantage plans to use the HHRG to assist claims processing. In addition, the HHAs and their vendors will be able to continue to advise patients of copayments due.

H. New Requirements Affecting Hospice Certifications and Recertifications

Section 3132 of the Affordable Care Act requires hospices to adopt some of MedPAC's hospice program eligibility recertification recommendations, including a requirement for a hospice physician or nurse practitioner to have a face-to-face visit with patients prior to the 180th-day recertification, and to attest that such a visit took place. The Affordable Care Act was enacted too late in the calendar year for the implementation proposals relating to these new requirements to be included in a Hospice Wage Index Proposed Rule. Therefore, these proposals were included in the Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices Proposed Rule. As such, we are responding to comments and issuing our implementation plan in this final rule.

In its March 2009 *Report to Congress,* MedPAC wrote that additional controls are needed to ensure adequate accountability for the hospice benefit. MedPAC reported that greater physician engagement is needed in the process of certifying and recertifying patients' eligibility for the Medicare hospice benefit. The Commission reported that measures to ensure accountability would also help ensure that hospice is used to provide the most appropriate care for eligible patients. MedPAC recommended these measures be directed at hospices that tend to enroll very long-stay patients. Specifically, MedPAC recommended that a hospice physician or advanced practice nurse visit the patient to determine continued eligibility prior to the 180-day recertification and each subsequent recertification, and attest that such visits took place. (MedPAC, *Report to the Congress: Medicare Payment Policy,* Chapter 6, March 2009, pp. 365 through 371.)

Section 3132(b) of the Affordable Care Act requires hospices to adopt MedPAC's hospice program eligibility recertification recommendations. Specifically, the Affordable Care Act amends section 1814(a)(7) of the Act to require that on and after January 1, 2011, a hospice physician or nurse practitioner (NP) must have a face-to-face encounter with every hospice patient to determine the continued eligibility of that patient prior to the 180-day recertification, and prior to each subsequent recertification. Furthermore, the Affordable Care Act requires that the hospice physician or NP attest that such a visit took place, in accordance with procedures established by the Secretary of the HHS. The Affordable Care Act provision does not amend the statutory requirement that a physician must certify and recertify a patient's terminal illness. By statute, only a physician (not a NP) may certify a patient's terminal illness, however, section 3132 (b)(2) of the Affordable Care Act allows a NP to furnish a face-to-face encounter; in the case where the NP provides the face-to-face encounter, the NP would then need to provide the clinical findings from that encounter to the physician who is considering recertifying the patient. This new statutory requirement will better enable hospices to comply with hospice eligibility criteria and to identify and discharge patients who do not meet those criteria.

Hospices which admit a patient who previously received hospice services (from the admitting hospice or from another hospice) must consider the patient's entire Medicare hospice stay to determine in which benefit period the patient is being served, and whether a face-to-face visit will be required for recertification.

As required by the Affordable Care Act, we made several proposals regarding § 418.22(a)(3), (a)(4), (b)(3), (b)(4), and (b)(5) in order to implement this new statutory requirement. We believe that required visits should be fairly close to the recertification date, so that the visit allows a current assessment of the patient's continued eligibility for hospice services. These visits can be scheduled in advance, particularly for those patients with diagnoses where life expectancy is harder to predict. As such, in § 418.22(a)(4), we proposed that hospice physicians or NPs make these visits no more than 15 calendar days prior to the 180-day recertification and subsequent recertifications, and that the visit findings be used by the certifying physician to determine continued eligibility for hospice care. We noted that this 15-day timeframe also aligns the timeframe for recertification visits with the timeframe required for the comprehensive assessment update, as specified in our Conditions of Participation (CoPs) at § 418.54(d). This timeframe requirement is also consistent

with the timeframe required for the review of the plan of care, as specified in our CoPs at § 418.56(d). We wrote that the 15-day timeframe provides a balance between flexibility in scheduling the visit and enabling a relatively current assessment of continued eligibility, while also allowing efficiency in update and review processes, as required by the hospice CoPs.

As noted earlier, the statute requires that the face-to-face encounter be used to determine the patient's continued eligibility for hospice services. We proposed that the clinical findings gathered by the NP or by the physician during the face-to-face encounter with the patient be used in the physician narrative to justify why the physician believes that the patient has a life expectancy of 6 months or less. Accordingly, we added this proposed requirement to § 418.22(b)(3) as subparagraph(v).

Because the statute also requires the hospice physician or NP to attest that the face-to-face encounter occurred and by statute only a physician may certify the terminal illness, at § 418.22(b)(4) we proposed that the face-to-face attestation and signature be either a separate and distinct area on the recertification form, or a separate and distinct addendum to the recertification form, that is easily identifiable and clearly titled. We also proposed that the attestation language be located directly above the physician or NP signature and date line.

The attestation is a statement from the certifying physician or from the NP which attests that he or she had a face-to-face encounter with the patient. If the face-to-face encounter was provided by a NP, the attestation should also include a statement that the clinical findings of that encounter have been provided to the certifying physician for use in determining continued eligibility for hospice care. We proposed that the attestation include the name of the patient visited, the date of the visit, and that it be signed and dated by the NP or physician who made the visit. Hospices are free to use other attestation language, provided that it incorporates these required elements. These elements must be included whether the visit is made by a NP or a physician. We note that it is possible that the certifying hospice physician is the same physician who made the visit.

As previously mentioned, we proposed to revise § 418.22 to incorporate these requirements and we proposed to add paragraphs (a)(4) and (b)(4) to implement the requirements for a face-to-face encounter with long-stay hospice patients and the attestation of that face-to-face encounter.

In requiring a timeframe in which the face-to-face encounter must occur, for consistency, we believe it is important to also clarify required timeframes for all certifications and recertifications. Long-standing guidance in our Medicare Benefit Policy Manual's chapter on hospice benefit policy allows the initial certification to be completed up to 14 days in advance of the election, but does not address the timeframe for advance completion of recertifications (see CMS Pub. No. 100–02, chapter 9, section 20.1). To clarify our policy in the regulations, and to be consistent with the timeframe for the newly legislated face-to-face encounter for recertifications, we proposed that both certifications and recertifications be completed no more than 15 calendar days prior to either the effective date of hospice election (for initial certifications), or the start date of a subsequent benefit period (for recertifications). This proposed timeframe also aligns with the CoP timeframe for updating the comprehensive assessment (§ 418.56(d)), and with the CoP timeframe for reviewing the plan of care (§ 418.54(d)). Finally, this proposed 15-day advance certification or recertification timeframe would also help ensure that the decision to recertify is based on current clinical findings, enabling greater compliance with Medicare eligibility criteria. We believe the new statutory requirements reflect the Congress' desire for increased compliance with Medicare eligibility and, in order to implement these provisions, we proposed to revise § 418.22(a)(3).

Furthermore, longstanding manual guidance stipulates that the physician(s) must sign and date the certification or recertification. However, the HHS Office of Inspector General (OIG) recently found that certifications for some hospice patients failed to meet Federal requirements, including the signature requirement (HHS OIG, "Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance with Medicare Coverage Requirements, September 2009"). In keeping with the Congress' desire for increased compliance with Medicare eligibility criteria, and to achieve consistency with the 180-day recertification attestation requirements, we proposed to add language to the certification requirements in our regulations to clarify that these documents must include the signature(s) of the physician(s) and the date each physician signed the document.

Additionally, with the new statutory requirements for a face-to-face encounter prior to the 180-day recertification, and for every recertification thereafter, it is important for hospices to easily identify which benefit periods require a recertification visit. Hospice patients are allowed two 90-day benefit periods followed by an unlimited number of 60-day benefit periods, so every 60-day benefit period is by definition beyond the 180-day recertification. Because we do not currently require that certifications or recertifications show the dates of the benefit period to which they apply, we proposed to add language to our certification and recertification regulations to make this a requirement for all hospices. While many hospices already include this information, there are some that do not. Having the benefit period dates on the certification would make it easier for the hospice to identify those benefit periods which would require a face-to-face encounter and would ease enforcement of this new statutory requirement.

Section 1814(a)(7)(A) of the Act requires a valid certification or recertification for Medicare coverage. Additionally, section 1814(a)(7)(D) of the Act now also requires a face-to-face encounter with patients who reach the 180th-day recertification. We proposed to revise our regulations to require that the physician's signature(s), date signed, and the benefit period dates be included on the certification or recertification because we believe this information is necessary to determine if these documents are valid, and to ease the implementation of the new statutory requirements. We believe these requirements are consistent with practices in the hospice industry, and we do not believe these proposals will be burdensome to hospices. As such, we proposed to add § 418.22(b)(5) to incorporate these signature and date requirements.

The following is a summary of the comments we received regarding the new requirements affecting hospice certification and recertification proposals.

Comment: Commenters asked for clarification of whether 180 days of hospice care must be provided before the face-to-face encounter was required, or whether the face-to-face was required when a patient enters the 3rd or later benefit periods. Several commenters suggested that we clarify the proposal so that the focus is on benefit periods, which they believe is consistent with the intent of the statute and the regulation, and which is easier to track; these commenters suggested we change

the regulatory text to reference election periods rather than days.

In contrast, other commenters suggested we reword the proposal so that an encounter and its accompanying attestation will be required after 180 days of hospice care and every 60 days thereafter. The commenters wrote that basing the encounter timeframe on benefit periods rather than actual days of care would result in some patients requiring visits after only a short time in hospice, which the commenters believe was not in keeping with CMS' intent to have patients with long lengths of stay assessed for continued eligibility. A commenter suggested that those 180 days must be continuous in order to trigger a face-to-face encounter.

Other commenters wrote that each new hospice admission should begin as day 1 for that hospice. One said that patients with a history of inappropriate admissions to different hospices should not cause the appropriate admissions to hospices to be penalized. Another wrote that although Medicare hospice is not fee-for-service, hospices still assume the risk of enrolling patients with high-cost medical needs based on the expectation that other patients will have lower cost medical needs. This commenter wrote that if a patient has had a previous hospice stay, and those days are counted toward the 180th-day recertification requirement, payment for those days was made to another hospice. The commenter also believes this invalidates an argument that the hospice has "accrued" sufficient funds to cover the additional costs of the required visits. The commenter suggested we not consider a patient's total hospice history in defining the 180th-day recertification requirement, but only focus on days of care within the specific hospice providing care. The commenter suggested that this would also eliminate problems related to accurately tracking time spent in hospice.

Another commenter wrote that if a patient had a significant break in hospice service, CMS should restart the time clock for the 180th-day recertification. Several commenters suggested that we consider each new terminal diagnosis to restart the clock as day 1; these commenters were referring to situations where a patient receives hospice care for a terminal diagnosis from which he or she recovers, and later receives hospice care for a different terminal diagnosis.

Other commenters asked for information about how to count the days when a hospice patient becomes eligible for Medicare in the midst of a non-Medicare hospice stay or when the patient has previously received hospice care outside of the Medicare hospice benefit.

Response: The relevant language in the Affordable Care Act reads, "* * * a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification * * *" The Medicare statute, as amended by the Affordable Care Act, does not define the term "180th-day recertification." For purposes of this provision, the Medicare statute also does not specifically address how the face-to-face encounter requirement should apply in the situation in which a beneficiary completes the first 90-day benefit period and is recertified for a second 90-day benefit period but does not receive 90 days of service in the second benefit period due to (for example) a revocation in the middle of the benefit period.

In interpreting the statutory term "180-day recertification," we considered the statutory scheme and the existing language used in the statute and in our regulations, all of which is structured around the concept of benefit periods which, by statute, cannot last longer than a maximum number of days (90 days for the first two and 60 days for subsequent benefit periods). The fact that the statute imposes a *maximum* number of days per period does not mean that an individual must receive hospice services for the maximum number of days before a statutory requirement can be imposed on subsequent benefit periods. For example, for payment to be made to a hospice provider with respect to a beneficiary, section 1814(a)(7) of the Act requires a certification (and recertification) at the beginning of each benefit period, the first two of which can last as long as 90 days each. Previously, we have interpreted these provisions to require a recertification at the beginning of each subsequent benefit period, even if the prior benefit period did not last the maximum number of days due to, among other things, the beneficiary's revocation under section 1812(d)(2)(B) of the Act. Thus, the regulatory language at § 418.22 requires certifications at the beginning of benefit periods rather than requiring certifications after a certain number of days of service was actually provided to a beneficiary.

For the foregoing reasons, we are defining the 180th-day recertification to be the recertification which occurs at the start of the 3rd benefit period—that is, the benefit period following the certification for a second, 90-day benefit period, regardless of whether the beneficiary received a full 90 days of service in the second 90-day benefit period. We note that, as one commenter wrote, this method of counting the time will also be easier for hospices to track. We also believe that the statute considers the patient's total hospice benefit period, rather than starting the clock at day 1 or period 1 for each new hospice or for a different terminal diagnosis. Furthermore, this method of counting benefit periods is consistent with how our systems operate when tracking Medicare hospice beneficiaries.

We agree with the commenter who wrote that hospices assume the risk of enrolling patients with high-cost medical needs based on the expectation that other patients will have lower cost medical needs. As such, we believe that hospices should consider costs of patient care in the aggregate, and not on a per-patient basis. Therefore, we did not argue in the proposed rule that a hospice "accrues" sufficient funds on a per-patient basis to cover the cost of the visit based on a patient having prior days of care with that hospice.

To illustrate this benefit period method of counting, if a hospice patient elected the benefit for the first time on June 1st, completed the 1st 90 day period (on August 30th), began the 2nd 90 day period, but revoked 30 days into the benefit period (on September 29th), and re-elected hospice the following January, the beneficiary would be in his 3rd benefit period. The 3rd benefit period would require a face-to-face visit at admission even though he had not received 180 calendar days of care.

The Medicare hospice benefit periods only apply to Medicare hospice patients, regardless of whether Medicare is the primary or secondary coverage. In other words, non-Medicare stays are not considered when counting benefit periods to determine when a face-to-face encounter must occur. The first Medicare benefit period would begin on the effective date of the first Medicare hospice election.

To clarify the language used about the timing of the requirement, we are modifying our proposal and the regulatory text to refer to the face-to-face encounter as being required prior to the 3rd benefit period recertification and each subsequent recertification.

Comment: Several commenters were concerned that they could not provide a face-to-face encounter within 15 days prior to the 180th-day recertification or each subsequent recertification. One wrote that this timeframe is a barrier to rational geographic batching of visits. They cited difficulties due to shortages

of physicians and NPs, particularly in rural areas. Several commenters said they would need to hire additional staff but were concerned about being able to successfully recruit a physician or NP because of shortages, particularly in rural areas.

One wrote that there are not enough well-trained hospice practitioners in this country to handle the potential volume of these visits and asked if we were concerned that the influx of providers required to make these visits would "water down" the quality of the assessments, and negatively impact the delivery of care to hospice patients.

Some noted that they have a part-time Medical Director with a busy private practice, who is simply not available to make the visits. One noted that in urban areas, traffic tie-ups add to the time required to make these visits. Others wrote that visits in rural areas require significant travel time, sometimes as long as 4 hours; one added that during these visits, their Medical Director would also be completely unavailable by phone for other patient and staff needs because in some remote areas there is limited cell phone service.

One asked if there was a requirement regarding the location(s) where a required face-to-face visit could occur. Another commenter wrote that the language of the proposed regulation at § 418.22(c)(4) implies that the practitioner must visit the patient at his or her home, rather than allowing the patient to come to the physician or NP. This commenter suggested that we change the regulatory text from "must visit" to "have a face-to-face encounter" as specified by section 3132 of the Affordable Care Act. A commenter noted that in some areas, patients would have to come to the physician, creating a burden on patients and families. Several commenters added that they cannot get frail or dying patients to the physicians because many cannot sit up in a car, and in rural areas, Emergency Medical Services (EMS) may be the only option for transportation.

Another commenter wrote that patients would not be able to afford the ambulance ride to a physician's office to make the visit; others were concerned that forcing a patient to travel to a physician was an undue hardship on both the patient and the family, would expose the patient to potentially infectious patients in the doctor's office, and could lead to exacerbation of symptoms such as severe pain or dyspnea.

One commenter suggested we consider the impact of the required visit on the family; another commenter wrote that the required visits would be an added stress to the family as they wait for confirmation from hospice staff that hospice care can continue. Another commenter wrote that if a patient required ambulance transport to a doctor's office, it would be an unreimbursed expense for the hospice, and asked if Medicare could cover the ambulance ride outside of the hospice per diem payment amount. One commenter said EMS will not cross county lines, yet 21 percent of the hospice's patients lived in a different county.

Another commenter asked if the hospice could discharge a patient if the patient or family refused the physician visit, or delayed it, and noted that with 15 days, there may not be time for adequate discharge planning. Several noted that some states have minimum discharge requirements, such as Alabama with a minimum 30-day requirement, which make the 15-day timeframe unworkable; one commenter asked how to handle the situation where the recertification visit determines that discharge is needed, but it occurs with less than 30 days to plan, as required by some State laws. This commenter asked that we allow for adequate discharge planning.

A few commenters asked what the hospice should do if the visit cannot be made due to scheduling difficulties, inclement weather, unsafe road conditions, or due to an emergency. Another commenter said that a hospice physician might not have an attending physician's dictation from the visit in time to make the attestation, and ask for more time to make the visits. One commenter wrote that the time constraints do not fit well with patients' conditions if their disease trajectories are in rapid decline. A commenter asked what would be the impact on a hospice if the required visit was not made in the allowable timeframe but was earlier or later. This commenter also asked if this requirement only affected Medicare hospice patients. Many commenters asked for more time to make the visit, suggesting 21 or 30 days.

Response: We appreciate commenters' input on the problems in scheduling these face-to-face encounters, and we recognize that rural hospices, in particular, may experience more logistical difficulty due to the shortage of physicians or NPs in some areas. Based on concerns and recommendations from the public comments on potential logistical issues, we are revising our proposed policy to change the visit timeframe from up to 15 days prior to the start of the 180th-day recertification, and each subsequent recertification, to a visit timeframe of up to 30 calendar days prior to the 3rd benefit period recertification, and each subsequent recertification. We believe this additional time will provide hospices with the flexibility they need to meet this Congressional mandate, to provide adequate time for discharge planning when indicated, and to accommodate other logistical issues discussed in the public comments.

We are unclear about the meaning of the comment related to State laws about discharge, and believe it may be outside the scope of this rule. We are only able to focus on the Medicare statute and payment regulations, which require that patients who are no longer eligible for the benefit be discharged. The statute does not allow us to pay for hospice care for patients who are not eligible for the benefit.

The regulations at § 418.26(d) require hospices to have a discharge planning process in place "that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill." The word "prospect" in this regulatory text indicates that hospices should be considering whether stable or improving patients might become ineligible in the future, and plan for a possible future discharge.

Hospices are required to follow State laws in additional to federal laws. However, we do not see the recertification requirement and any State discharge requirements as being in conflict.

If a patient or family member refuses to allow the hospice physician or NP to make the required visit, a hospice could consider discharge for cause, as the refusal would impede the hospice's ability to provide care to the patient. The hospice would need to follow the procedures for discharge for cause, which are given in § 418.26.

In response to the comment suggesting that we change the proposed regulatory text at 418.22 (C)(4) from "must visit" to "have a face-to-face encounter" as language of the proposed regulation implies that the practitioner must visit the patient at his or her home, rather than allowing the patient to come to the physician or NP, we are revising the proposed language. We believe that the Affordable Care Act allows hospices the flexibility for patients to have a face-to-face encounter with a hospice physician or nurse practitioner. We are revising the regulatory text at § 418.22(a)(4) to now read, "As of January 1, 2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter * * *" We expect that hospices will not require patients to

come to the hospice physician or NP for the encounter if doing so would exacerbate symptoms or otherwise jeopardize the patient's well-being; the hospice Conditions of Participation (CoPs) in § 418.100(a) require that hospices provide care that optimizes patient comfort, and is consistent with the patient's and family's needs and goals. All patient transport must occur within the context of optimizing patient comfort and meeting the specific needs and goals of patients and their families. If transportation to a hospice physician would not optimize patient comfort and/or meet the goals and needs of the patient and family, the hospice physician or NP would need to travel to the patient. If a hospice patient travelling to the hospice physician or NP required ambulance transportation because of his or her medical condition, the ambulance transportation would be included in the hospice per diem; it could not be billed to patient.

We believe that the face-to-face encounters will not be an added stress to family members if they know they are a routine part of the hospice recertification process, and if the family understands that the visit has the potential to improve the quality of care for their loved one.

In response to the commenter's concern that the patient's attending physician's dictation might not be available to the hospice in the 15 days prior to the recertification, and this would prevent the hospice from meeting the 15-day timeframe that was originally proposed, we believe that the commenter appears to misinterpret the statutory requirement. Pursuant to section 3132(B) of the Affordable Care Act, a hospice physician or hospice NP must perform the encounter. The definition of hospice physician is addressed later in this section.

In response to the comments asking for clarification about to which patients the face-to-face encounter requirement applies, we note that it only applies to Medicare hospice patients.

Finally, we proposed clarifying some language in our benefit policy manual and aligning timeframes so that recertifications could not be completed more than 15 days prior to the start of the subsequent benefit period. While the entire recertification cannot be completed more than 15 days prior to the start of the benefit period, we are clarifying that the face-to-face encounter and its accompanying attestation are only parts of the recertification, and therefore can be completed up to 30 calendar days prior to the start of the 3rd benefit period recertification and each subsequent recertification.

Comment: Several commenters have asked if the hospice face-to-face encounter is billable, and if so what reimbursement code should be used. A number of commenters wrote that their hospices do not have the resources to accomplish this if the visit is not billable; one wrote that this requirement could have the potential to drive smaller providers out of the market. They wrote that this requirement would be a financial burden, especially to rural providers, in the face of reductions due to the budget neutrality adjustment factor (BNAF) phase-out and future market basket cuts, declining charitable donations, increased costs, and demands for competitive wages. A few commenters mentioned that hospices will be absorbing more than a 14 percent reduction in their Medicare and Medicaid reimbursement levels over the next 10 years; they wrote that these reductions are especially difficult for the hospice community since hospice programs are disproportionately dependent upon Medicare and Medicaid for reimbursement. These commenters believe the upcoming payment reductions place increasing financial pressure on hospices that seek to deliver quality care and comply with additional administrative and regulatory requirements.

A number of commenters wrote that they could not afford this unfunded mandate. One rural commenter noted that their reimbursement is already lower due to wage index adjustments, and yet the costs of these required visits will fall more heavily on rural providers, with long distances to see patients; this commenter believes the burden to rural hospices was becoming "almost insurmountable." Commenters also mentioned the administrative costs of coordinating the visits, of changing existing forms and documents, and of increased liability risks, and several believe that these are not included in the current hospice reimbursement. Another noted that hospices would be expected to pay physicians or NPs for their travel time, visit time, and mileage, and would have additional administrative costs while receiving the same per diem payment amount. One commenter said that his hospice would be forced to reduce services to patients to pay for these visits. One commenter wrote that this requirement creates a 2-tiered system where providers are compensated better for patients under the 180-day recertification requirement than for beneficiaries who require a face-to-face encounter.

Several said that they would have to hire someone full-time to make the visits, which would create significant financial hardship without reimbursement; one wrote that those monies would be better spent on providing quality care and on fair wages for employees. A few added that having a physician or NP spend hours traveling to see patients would be a waste of scarce human resources in areas where there are physician or NP shortages. A few mentioned that the net result would be less patient care, and more time spent on paperwork.

Nearly all commenters suggested some form of reimbursement for the visit, with one commenter writing that all physician visits mandated by payers should be billable separately by the physician directly to the payer for reimbursement. One commenter was concerned that because these required visits are medically unnecessary, there would be no reimbursement for them, yet hospices would still incur costs from making the visits. Another commenter added that many physicians or NPs would order tests such at CAT scans or lab tests to obtain results that justify recertification of patients, and yet would not receive reimbursement for these tests.

A few commenters suggested that any part of the visit that becomes medically necessary, including those where the doctor changes the plan of care (POC) or makes medication adjustments, should be billable. One commenter asked if a hospice could bill the patient for the face-to-face visit if it was not covered.

One commenter wrote that when the Medicare hospice benefit was originally designed, physician face-to-face visits were viewed as an encounter for additional counseling, education, information, and support. The commenter asked why any physician face-to-face visit would not be billable. Another commenter cited our regulations at § 418.304, and asked if the face-to-face visit was considered part of the establishment and updating of the plan of care, or is it outside the services listed, and could be billed separately. If the visits are part of the per diem amount, the commenter encouraged CMS to review the payment rates and increase the per diem to reflect this new, mandated service.

A number of commenters believe that the face-to-face requirement was beyond the administrative services provided by the hospice Medical Director, and outlined in the hospice claims processing manual in section 40.1.1 (see Internet Only Manual, 100–04, chapter 11). Several commenters wrote that since active clinical work and a comprehensive analysis will be required of the physician (as distinguished from simple documentation in the medical

record), they believed that a billable visit is appropriate. Another wrote that while the medical decision-making is primarily directed at determining prognosis, in many cases, changes in medication and patient management may also be suggested. A different commenter wrote that the face-to-face encounter requires direct patient care services, including a comprehensive clinical assessment and is comparable to the billing for evaluation and management services provided in other settings and should be reimbursed as such. Another commenter wrote that there is no precedent for a physician to be required by law to provide a thorough medical assessment of a seriously ill patient and be constrained from coding, billing, or seeking usual and customary reimbursement for such care.

For any portion of the visit that is billable, commenters asked how to document that billable portion, including whether to make one note or two. A number of commenters wrote that their anticipated costs for the visits would far exceed any reimbursement, particularly given the travel time and mileage costs. Another also noted that there is currently no physician reimbursement for Medicaid patients visited by the hospice physician.

A few commenters noted that NP services that are equivalent to physician services are not currently billable unless the NP is the patient's attending physician. One asked if this would change under the proposed rule.

A commenter wrote that the Medicare CoPs speak to the actions of a physician providing medical care to a hospice patient as separate from the role of the Medical Director, and that these services are accounted for differently in the per diem payment rate. This commenter wrote that the roles of these two physicians are distinct, and that CMS should consider providing adequate reimbursement for the services being required. Another commenter asserted that if Medicare wants quality healthcare, Medicare must allow practitioners to bill for their time.

A few commenters wrote that there was an established precedent in Skilled Nursing facilities that encounters to meet mandated requirements are billable and reimbursed by CMS, beyond the administrative duties of the Medical Director. Given this information, they asked us to clarify if the mandated visit would be billable.

A commenter asked if we plan to track face-to-face encounters with a particular CPT code, and if it should be reported on the claim. Another commenter asked if we are concerned about the distortion of the actual cost associated with providing care to hospice patients if these visits are not captured on the claim. Some commenters asked us to devise a HCPCS code to compensate the hospice physician or NP for the time and mileage for making these visits. Others asked us to develop a billing code that would include mileage costs and travel time, and increase the per diems to reflect the additional administrative costs related to the proposal. One recommended a separately reimbursable fee schedule amount specific to face-to-face encounter visits.

Response: We appreciate the commenters concerns about the financial effects of the face-to-face requirement. However, the billing regulations for hospice do not allow for physician reimbursement for administrative activities of physicians. The certification or recertification of terminal illness is not a clinical document, but instead is a document supporting eligibility for the benefit. In the 1983 Hospice Care Final Rule, certifications of terminal illness were described as "simply determinations as to the patient's medical prognosis, not the plan of care or the type of treatment actually received" (48 FR 56010). As such, the certification or recertification of terminal illness has been excluded from separate physician reimbursement and has been considered an administrative activity of the hospice physician. The face-to-face requirement is part of the recertification, and therefore is an administrative activity included in the hospice per diem payment rate. In contrast, the SNF bundle specifically excludes the services of physicians and other advanced practiced disciplines including NPs. Therefore, SNF physicians or NPs can bill for mandated encounters, as these visits are not part of the bundled payment.

The hospice face-to-face encounter is an administrative requirement related to certifying the terminal illness mandated by the Affordable Care Act. By itself, it would not be billable, as it is considered administrative, as explained above and in section 40.1.1 of the Claims Processing Manual (Internet Only Manual 100–04, chapter 11): "Payment for physicians' administrative and general supervisory activities is included in the hospice payment rates. These activities include participating in the establishment, review and updating of plans of care, supervising care and services and establishing governing policies." Determining continued patient eligibility would fall under the "general supervisory services" described at § 418.304(a)(1), rather than under review and update of plans of care described at § 418.304(a)(2).

However, if a physician or nurse practitioner provides reasonable and necessary non-administrative patient care such as symptom management to the patient during the visit (for example, the physician or NP decides that a medication change is warranted), that portion of the visit would be billable. We believe that allowing for this type of billing will not only increase the quality of patient care, but also will help defray the costs to hospices of meeting this requirement. Hospices may not bill patients for face-to-face encounters or for any medically necessary physician services provided during the encounter, as these are hospice services. Billing for medically necessary care provided during the course of a face-to-face encounter should flow through the hospice, as the physician or NP who sees the patient is employed by or where permitted, working under arrangement with the hospice (for example, a contracted physician).

The commenter who wrote that hospices cannot bill for physician services provided by a NP unless the NP is the attending physician is correct. The regulations at § 418.304(e) only allow nurse practitioner services to be billed when the nurse practitioner is the patient's designated attending physician. In order to be billable, this regulation also requires that the NP must provide medically reasonable and necessary services that are physician level services, and not nursing services (that is, in the absence of a nurse practitioner, the services would be provided by a physician and not by a nurse). The regulation also excludes billing for services related to the certification of terminal illness.

The hospice physician or NP that has the face-to-face encounter with the patient should ensure that any clinical findings of the visit(s) are communicated back to the interdisciplinary group (IDG), for use in coordinating the patient's care. This is particularly true if the physician or NP discovers unmet medical needs during the billable or non-billable portion of the visit, so that the IDG can coordinate with any attending physician. Hospices are not to provide services that are duplicative of what the attending physician is doing and are responsible for coordinating with the attending physician if they provide any reasonable and necessary patient care when having a face-to-face encounter. If there is a billable portion attributable to the visit, hospices must maintain medical documentation that is clear and precise

to substantiate the reason for the services that went beyond the face-to-face encounter, and which apply to the billed services; this can be done in one note.

At this time, we do not plan to track these required visits with a special CPT code, or to create any additional HCPCS codes related to these visits. In the coming years, we will be reforming the hospice payment system, and will be analyzing hospice costs and reimbursements to ensure that providers are being paid fairly.

We are unclear about the meaning of the comment that indicated that there is currently no physician reimbursement for Medicaid patients visited by the hospice physician. However, we note that the Medicare hospice benefit reimburses hospice physicians and attending physicians for reasonable and necessary care provided to hospice patients, whether the patients are dually eligible or not. If the commenter is referring to patients who have Medicaid only, we suggest that the commenter see his or her State Medicaid Manual, particularly sections 4305.05 and 4307, which deal with the Medicaid hospice benefit and with physician services, respectively. The paper-based State Medicaid Manual can be accessed through our Web site, at *http://www.cms.hhs.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021927.*

Finally, the hospice face-to-face encounter is only required for recertifications when the patient is in the 3rd benefit period or beyond. By definition, hospice patients are terminally ill, with a prognosis of 6 months or less if, the illness runs its normal course. Therefore, the majority of hospice patients should not require a face-to-face encounter.

Comment: A number of commenters wrote that hospices cannot currently access accurate information in a timely manner to determine the status of previous hospice services. The commenters expressed concern that a hospice might admit a patient without having complete or accurate information about previous hospice services, and therefore not be aware that a face-to-face encounter could be required, resulting in denial of payment. Commenters stressed that without timely, accurate information, it is impossible for hospices to comply with this regulation.

Several asked if the fiscal intermediary standard systems (FISS) was available 24 hours per day, 7 days per week, or if the fiscal intermediaries (FIs) or Medicare Administrative Contractors (MACs) could impose down times for maintenance, holidays, weekends, or other reasons, noting that many hospice admissions take place after hours and on weekends, and recommended that we review FISS operating hours to ensure that it is available at all times. A few wrote that FISS cannot be accessed via secure internet site from any computer, but that hospices are required to purchase individual licenses and connection capabilities for each computer. One wrote that if a patient is discharged alive from a hospice more than six months from the inquiry date in the Eligibility Home Health Inquire (ELGH), the ELGH screen fails to reflect the previous hospice election, inaccurately suggesting to the provider that the patient had never elected hospice. One noted that using the look-up systems to determine a patient's hospice history is cumbersome. This commenter also asked how far back benefit period records are kept within FISS. Several commenters noted that many hospices do not bill in a timely fashion, which places the receiving hospice at risk even if the Common Work File (CWF) or other resources are dutifully checked at time of admission. One commenter asked that we explore options to access the FISS system, and to ensure timeliness and availability of the complete hospice history.

A few commenters asked who would be responsible for monitoring the patient's time in hospice, to know if a face-to-face encounter was required. The commenters stated they would not know the patient's history otherwise. One asked how a hospice would know when the last face-to-face encounters took place on patients who are transferred or who came from out of the area. This commenter also asked if a hospice could rely on a previous face-to-face encounter if the patient is being transferred from another hospice within 60 days of the last face-to-face encounter. Several commenters asked if the Provider Statistical and Reimbursement Report (PS&R) would be able to provide benefit period information.

Some also wrote that hospices should not be held accountable for failure to provide a visit if the data systems were unable to provide them with the accurate and timely information needed, or if the provider miscalculated the certification or recertification dates and/or face-to-face visit requirement because of inaccurate system information. Several asked that we provide clear guidance as to what would constitute a "best effort" to secure a patient's full hospice history for establishing the proper benefit period, and "hold harmless" those providers who have met the "best effort" standard. One commenter suggested we delay implementation of the face-to-face requirement until there is a CMS system in place that is available 24 hours per day, 7 days per week, and that providers not be responsible for knowing about prior hospice use if the data are not available in FISS. This commenter suggested that FISS operating hours be reviewed and that CMS consider requiring the FI/MAC contractors to have FISS available for longer hours and on nights, weekends, and holidays.

Response: Hospices are responsible for verifying which benefit period a patient is in at admission by using the CWF to determine the beneficiary's benefit period. The CWF is used because the FISS is responsible for the actual processing and payment of claims, and does not track benefit periods. There are several CWF query systems to determine which benefit period a hospice patient is in. Both ELGH and Health Insurance Query for Home Health Agencies (HIQH) give real time data; hospices should be using the CWF queries for the most accurate beneficiary information. If providers are unsure how to use the CWF queries, they should contact their MACs.

Because CWF has 9 host sites, a provider would have to search through up to 9 databases to determine if a patient who moved from another part of the country received prior hospice care; a beneficiary's records are only in 1 of the 9 databases, so as soon as the beneficiary is located, the search may cease. Although this may be cumbersome, the CWF is required to be available from 6 a.m. to 6 p.m. Monday through Friday and 6 a.m. to noon on Saturdays, by the time zone of the host site. We strive to have the CWF available beyond these minimum timeframes, but there are some regular downtimes: every Saturday, usually from 4 p.m. to past midnight, Sundays from 7 p.m. to 9 p.m. (central time), and the third Sunday of every month from 12 a.m. to 4 a.m. (central time).

The PS&R system cannot currently provide the information needed to determine the current benefit period, and the revised system is still under development.

If CWF is not available, hospices have another option for verifying a patient's hospice benefit periods, using an inquiry that is usually available 24 hours per day, 7 days per week, 365 days per year: the Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS), specifically the 270/271

transaction. Those hospices that file their claims through a clearinghouse, or which have a direct connection to CMS, or whose MAC provides an Internet portal, would have access to the HETS system as a data source for their eligibility. The HETS 270/271 inquiry is in real time, but claim information lags up to 24 hours. It is also a national database, therefore there is no need to search multiple host sites. A 270 transaction is a transaction query and a 271 transaction is the response to the user. A 270 transaction query for a patient's benefit periods will return up to 3 years of data, showing all prior hospice benefit periods. This query system can be used if the CWF system is not available; providers can go to *http://www.cms.gov/HETSHelp/* for information on the HETS 270/271 transaction, or they can call 1–866–534–7315. Therefore, hospices have multiple ways of verifying a patient's prior hospice history to determine which benefit period the patient is in.

If a beneficiary has received hospice care at another provider, commenters are correct that the CWF may not be up-to-date if that previous provider has not billed promptly. We share commenters' interest that the benefit period information available via the CWF or the 270/271 transaction should be as up-to-date as possible. Hospices have a financial incentive to bill in a timely fashion, and in our claims processing manual, we have encouraged providers to file their Notice of Elections as soon as possible after an election; similarly, we have often encouraged providers during the public CMS Open Door Forum discussions to bill in a timely fashion. In addition to checking our data systems for benefit period information, hospices can also ask the beneficiary (or his or her representative) if he or she has received hospice care previously. In putting forth their "best effort" to identify whether a patient requires a face-to-face encounter, hospices should not rely solely on data systems to determine the benefit period, but should also talk with the patient or representative where possible, and should document the information they find along with the methods used to find the information.

Several commenters suggested that we "hold harmless" those who rely on the CWF response information to determine whether a face-to-face encounter is required. We are unable to provide flexibility as the statutory language in the Act requires a certification or recertification in order for Medicare to cover hospice days of care. If a hospice has not had a required face-to-face encounter, then the recertification would not be complete, and we would be unable to cover the days of care that were under that recertification.

However, we believe that the flexibility afforded to hospices in determining benefit period data eliminates most situations where a hospice does not have accurate benefit period data. Furthermore, we believe that in many cases, the patient or his or her representative will know if hospice care was provided previously. Based on analysis of our FY 2007 claims data, about 20 percent of all hospice beneficiaries reach benefit period 3 or later, and thus would require a face-to-face evaluation. Of that 20 percent, only a fraction of those beneficiaries might have benefit period data that are not up-to-date in the systems, and which cannot be verified with the patient or representative. In addition, of that fraction, another fraction will show benefit period 1 or 2, rather than period 3 or later, due to having prior hospice care. Therefore, given the historical data, we do not believe that this situation will be common or that there is a need to hold hospices harmless.

The Affordable Care Act requires that a hospice physician or NP have a face-to-face encounter with any patient that it admits in the 3rd or later benefit period; prior face-to-face encounters performed by previous providers cannot be used to substitute for a face-to-face encounter that is required by the current hospice. In a transfer situation, the benefit period does not change, so the originating hospice would have been responsible for any required face-to-face encounter if the patient was in the 3rd or later benefit period. When a patient is in the 3rd or later benefit period transfers to a new hospice, the receiving hospice must recertify the patient, but it does not have to have a face-to-face encounter for that current period if it can verify that the previous hospice provided the visit.

In response to comments asking that we delay the effective date, we note that we are unable to delay implementation of the face-to-face requirement since the statutory language requires that it begins on January 1, 2011.

Comment: Several commenters were concerned about requirements when a patient with a prior hospice stay requires a visit upon admission to a new hospice. This group of commenters along with others also noted that during a time of crisis, the need to admit the patient for pain and symptom control should take precedence over provision of any required face-to-face encounter. Another commenter was concerned that requiring a face-to-face encounter would create barriers to timely access and increase costs in situations where a patient elects hospice, revokes, re-elects, revokes, and re-elects in a short time period. Recertification at this 3rd benefit period would require a face-to-face encounter. One commenter noted that if a visit is required at admission, it may unduly delay needed care or prove impossible prior to death if the patient is actively dying. Several commenters wrote that if a patient requires a face-to-face visit at admission, it will likely result in a break in service until the physician can make the visit; one suggested this may lead to patient and family complaints. This commenter asked whether these complaints should be referred to CMS, since the commenter has no control over this legislative mandate, and added that denial of service is a serious issue, especially if the patient is near death.

Several commenters asked that we waive the face-to-face requirement for patients who, because of prior hospice enrollment, require a face-to-face encounter at admission, but whose death is imminent or who die within a week.

One commenter asked what would be required if a patient transferred near the end of the 2nd 90-day period (for example, at day 175), and the recertification was not completed. The commenter wondered how much time the receiving hospice would have to complete the face-to-face encounter. Another commenter asked if providers could rely on the previous hospice's face-to-face encounter if the patient was being transferred from another hospice within 60 days of the last face-to-face encounter, and wondered how hospices would know when the last face-to-face encounter took place. A commenter suggested that the initial and comprehensive assessment be communicated to the Medical Director, to replace the need for a face-to-face encounter, when a patient would require one upon admission. When a visit is required upon admission, several commenters suggested timeframes after admission to allow the visit, including 2 days, 5 days, 15 days, and 21 days.

Response: During a time of crisis, the need to admit a patient and provide pain and symptom control is a priority. Since this is a new admission, whether the patient is coming from another provider type, from home, or is transferring from another hospice, we understand that the receiving hospice may not have up to 30 calendar days prior to the start of the benefit period to have a face-to-face encounter. However, the statute requires that the visit occur "*prior* to the 180th-day recertification and each subsequent recertification

* * *" (emphasis added). We do not have the ability to waive a statutory requirement or to allow the initial and comprehensive assessments to replace the required encounter.

As noted previously, in a transfer the benefit period remains the same. When a patient in the 3rd or later benefit period transfers to a new hospice, the receiving hospice must recertify the patient; however, since the benefit period does not change with a transfer, the receiving hospice does not have to have a face-to-face encounter for that current period if it can verify that the previous hospice provided the visit. According to the hospice CoPs at § 418.104(e), the sending hospice must forward to the receiving hospice the patient's clinical record, which includes the certifications and recertifications of terminal illness, if requested. The clinical record can be used to verify whether or not the sending hospice provided any required face-to-face encounters.

Our regulations describe recertification as a process. We currently allow 2 calendar days after a period begins for a hospice to provide either a written or a verbal certification or recertification. If a verbal certification is provided, the written certification, including the narrative, must be completed prior to filing the claim. Therefore, certification or recertification can occur at a point in time, but often occur over a period of time.

In response to the comment asking whether complaints should be referred to CMS, we note that hospices are free to refer complaints to us at CMS or to Congressional representatives. We welcome input, and would consider it when evaluating our policies given the constraints of the statute. We appreciate the concerns that commenters have raised about providing a visit upon admission, particularly in rural areas. We will be examining this issue to see how it fits with the statutory and regulatory language. In the meantime, we will monitor the program for any unintended consequences.

Comment: A number of commenters requested flexibility in who could make the face-to-face visits, and asked us to clarify our interpretation of "hospice physician or NP". One asked if there was a distinction between the physician as an employee (who received a W–2 from the hospice), a contract physician (who receives a Form 1099 from the hospice), or a volunteer. Others asked if certification in hospice and palliative care was required, or if full-time, part-time, or per diem status mattered. One commenter wrote that the proposal to require a "hospice physician or nurse practitioner" to perform the face-to-face encounter was materially different from the language in section 3132 of the Affordable Care Act. This commenter suggested that we take an approach consistent with the definition of "physician designee" in § 418.3, and allow the patient's primary care physician, specialist, hospitalist, hospice Medical Director, or other qualified physician to perform the visit, provided that physician is willing to certify eligibility for the benefit and communicate the encounter results to the hospice certifying physician.

Several commenters suggested allowing a Physician's Assistant (PA) to perform the face-to-face encounter; a few noted that in rural areas, PAs are more common than NPs. Other commenters asked if a hospitalist could perform the visit. A third commenter wrote that if a physician can collaborate with a NP to make the visit, why not also with a registered nurse (RN). One commenter said that the requirement that a physician make the visit was an insult to both the RN case manager and to the patient, and suggested that the RN case manager is capable of making the visit. The commenter added that the proposed rule sends the message that an RN case manager is good enough when it merely involves a human being's needs, but when it comes to reimbursement/money, a physician is required. Another commenter wrote that the Scope of Practice and Nurse Practice Acts for all Registered Nurses specifically allows for physical assessment and expects pathophysiology expertise. The commenter also added that RNs are as equally qualified as a NP to perform these assessments and report findings to the hospice Medical Director to establish eligibility.

Another commenter raised concerns about using a contracted physician to make the visit; this physician may be trained and may have reviewed the chart, but it would likely be the first time this doctor has seen the patient. The commenter wrote that based on the nurse's notes, the patient has a steady decline, but if the physician sees the patient on a good day, the physician may not believe that the patient is eligible for hospice care, and may recommend discharge. The commenter believes and highly respects the qualifications of physicians, in this case the trained nurse, certified in hospice and palliative care, has been seeing the patient multiple times per week, and is a better judge of the patient's eligibility.

Several commenters asked if NPs could sign the certification or recertifications. A few commenters asked that we allow medical residents or fellows to provide the face-to-face visits if they are rotating through a hospice or in a setting where hospice patients reside. One commenter asked if hospices can contract with physicians to only provide the face-to-face encounters, and what employment requirements would those physicians need to meet. Another commenter asked if a hospice could have volunteer physicians make the visit or contract with another hospice, to have their physician or NP make the visit.

A few commenters recommended that a hospice be allowed to contract with a NP for the purpose of making required face-to-face visits, rather than requiring a W–2 employment relationship only. A commenter also asked that we clarify that NPs providing the face-to-face visit must meet Medicare's general qualifications for a NP and must be licensed by the State in which they are practicing, but that they do not have to have a particular specialty certification or credentials in order to be considered a "hospice nurse practitioner" for purposes of providing the face-to-face visits. A few commenters asked if the NP must be the patient's designated attending in order to make the required visit. One asked if hospices could contract with a NP even though the hospice did not have a contract with the physician supervising the NP. The commenter added that in her area, there were competing hospitals, which could create a conflict of interest if the hospice Medical Director was associated with one hospital and the contracted NP with a competing hospital. Another commenter asked that we clarify how supervision will work for contracted NPs whose role is to make the face-to-face visits.

Other commenters suggested that advanced practice nurses such as Clinical Nurse Specialists (CNS) could make the visit and that allowing them to do so would decrease the burden of the visits in areas where there are shortages of physicians or NPs, enabling them to meet the requirement. One noted that CNS can become certified in hospice and palliative care.

A number of commenters suggested allowing the patient's attending physician to perform the required visits. These commenters noted that in many rural areas, the hospice physicians do not assume direct medical care of the hospice patients, but instead determine continued eligibility through review of clinical findings reported by the members of the IDG. The commenters wrote that the attending physicians are involved in these hospice patients' care, have a history with the patient, and may

be geographically closer to the patient. In advocating for allowing attending physicians to make these required visits, one commenter noted that because of historical knowledge and perspective, the attending physician's medical opinion should be deemed relevant and critical to the delivery of hospice care, and indeed his or her signature is required on the initial certification. One commenter stated that the proposed regulation fails to recognize the ongoing relationship between an attending physician and the patient, by excluding attending physicians from the encounter. Another wrote that attending physicians would make better use of resources and be more in line with the emphasis placed on attending physician involvement in the 2008 Medicare CoPs for hospices. A different commenter wrote that allowing the attending physician to make visits would be in keeping with Medicare's Home model. A few asked if hospices could contract with the patient's attending physician to make the visit, and if so, would the billing be through the hospice or through Part B. One suggested that such billing should flow through the hospice.

A commenter suggested that for hospice patients residing in a facility, the facility physician should be allowed to perform these face-to-face visits and report them to the physician who will sign the plan of care; the commenter added that this would promote coordination of care between the facility and hospice.

A few commenters noted that in some rural areas, the only available physicians are employed by Rural Health Clinics (RHCs) or Federally-Qualified Health Centers (FQHCs). Federal requirements applicable to both of these provider types create barriers to hospices wishing to work with them. One commenter stated that Medicare has recommended that RHC physicians treat hospice patients after business hours in a separate space other than the RHC, billing under Part B, which further inhibits health care provider accessibility. Another commenter asked for additional conversations with us to discuss this issue.

A commenter stated that if a "hospice physician" is interpreted to mean a doctor who is employed by or under contract with a hospice, or the patient's attending physician, hospices will begin making contracts with doctors to pay a fee for eligibility certifications whenever the hospice staff physicians are unable to have the encounter. The commenter believed that the potential for abuse is obvious, with payment given for favorable eligibility determinations.

Response: The statutory language in the Affordable Care Act limits the disciplines of those who can provide a hospice face-to-face encounter to a hospice physician or NP. A few commenters asked why RNs could not meet the requirement, particularly since they are involved in the patient's ongoing care. This statutory provision was based upon a recommendation made by MedPAC. In its 2009 *Report to Congress,* MedPAC reported that a panel of hospice experts agreed that more physician accountability was needed in the certification and recertification process. They wrote that the panel discussed a tension that can exist between the physician and nonphysician hospice staff which can lead to inappropriate recertification in some cases. MedPAC's panelists believed that physicians sometimes deferred too much authority for making eligibility decisions to nonphysician staff. They added that by virtue of their day-to-day contact with patients, these staff members may form emotional attachments with patients that can color their view and their charting of a patient's continued eligibility for hospice (Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy,* Chapter 6, March 2009, page 365, available at *http://www.medpac.gov/documents/Mar09_EntireReport.pdf*). The panelists' comments were part of the impetus for MedPAC's recommendation regarding the face-to-face encounter which the Congress enacted in the Affordable Care Act. Accordingly, by law, RNs (other than NPs) are not allowed to perform the face-to-face visit. This is in no way intended to insult or to diminish the importance of RNs in hospice care—they are key to patient care in hospice, and provide quality, compassionate care to those at end-of-life.

A commenter was concerned about a scenario where a contracted physician who is unfamiliar with the patient might see the patient on a day when the patient is doing well, clinically, and thus recommend for discharge when the patient is in fact eligible. The determination of eligibility involves considering the terminal illness, related conditions, co-morbidities, functional status, clinical indicators, laboratory results, etc. We believe the potential for a truly eligible terminally ill patient being found ineligible because he or she was doing well clinically, on the day of the encounter, is unlikely. Even so, the decision to discharge the patient is not made simply by the contracted physician, but involves the members of the IDG and the patient's attending physician. Hospices should already have policies and procedures in place for handling a situation where there is disagreement about continuing eligibility.

PAs and CNSs are not authorized by the Affordable Care Act to perform the face-to-face visit. Moreover, section 1814(a)(7) of the Act explicitly prohibits NPs from certifying or recertifying hospice patients, and limits this function to physicians only. Therefore, we cannot adopt a policy to allow NPs to certify or recertify patients without change in the statute.

Hospices cannot routinely contract with NPs, because NPs fall under nursing, which is a core service. The only situations under which a hospice could contract with a NP would be under extraordinary circumstances or if the NP service is highly specialized. Extraordinary circumstances generally would be a short-term temporary event that was unanticipated, and would not include face-to-face encounters, which are administrative in nature and which are usually planned. Examples of allowable extraordinary circumstances might include, but are not limited to, unanticipated periods of high patient loads (such as an unexpectedly large number of patients requiring continuous care simultaneously), staffing shortages due to illness, receiving patients evacuated from a disaster such as a hurricane or a wildfire, or temporary travel of a patient outside the hospice's service area. Hospices may qualify for an "extraordinary circumstance" exemption when they believe that the nursing shortage has affected their ability to directly hire sufficient numbers of nurses. For details on this waiver, please see the letter from CMS' Survey and Certification group found at *http://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter10_31.pdf.*

Hospices can employ NPs on a full-time, part-time, or per diem basis if needed to have face-to-face encounters. As long as the NP is receiving a W–2 form from the hospice, or is volunteering for the hospice, the NP is considered to be employed by the hospice.

Commenters asked about other physicians who could be considered "hospice physicians" who could be used to meet the face-to-face requirement, including attending physicians. We believe that to be a "hospice physician", a physician must be either employed by or working under arrangement with a hospice (*i.e.,* contracted). Section 418.3 defines a hospice employee as someone who is receiving a W–2 form from the hospice or who is a volunteer. We agree

with commenters that the attending physician has had a history with the patient, has signed the initial certification, and has typically remained involved in the patient's care while the patient is under the hospice benefit. We do not wish to diminish this physician's role; however, the regulations have considered services of attending physicians to be outside of the hospice benefit (which is one reason why their services are billed to Part B rather than through the hospice to Part A), and therefore we cannot include the attending physician as a "hospice physician." By limiting "hospice physician" to those physicians who are employed by or working under contract with a hospice, we also increase accountability, as the hospice is in control over its employees and contracted physicians, but not over an outside attending physician who might have the encounter. Furthermore, as part of the effort to increase accountability, we are clarifying that the hospice physician who has the face-to-face encounter must be the same physician who is composing the narrative and signing the certification. Given that the hospice is ultimately responsible for the certification, part of which is the face-to-face attestation, the hospice needs control over the timing of the staff visit, and over the preparation and review of visit documentation, which is used for the narrative and to inform the decision whether to recertify or not.

Other commenters suggested that non-hospice physicians other than attending physicians should be able to make the visit (for example, hospitalists, specialists, primary care physicians, etc). In addition to not meeting the statutory criteria of being a "hospice physician," we agree with the commenter who wrote that allowing physicians who are not involved with the patient's overall care to have the visit could lead to abuse, where an unscrupulous doctor might continue to support eligibility of ineligible patients for a fee. Additionally, we do not believe that allowing any physician to have the required face-to-face encounter would be appropriate because determining eligibility for hospice care requires knowledge of the patient's complete medical situation, including the terminal illness, related conditions, and other co-morbidities. Medical residents or fellows who are rotating through a hospice may provide the required face-to-face encounter if they are employed by the hospice or are working under contract with the hospice, and if they will be composing the narrative and signing the recertification.

Physicians or NPs who volunteer for a hospice are considered employees, and could make the required visits. No payment is made for physician or NP services furnished voluntarily. However, some physicians and NPs may seek payment for certain services while furnishing other services on a volunteer basis. Payment may be made for services not furnished voluntarily if the hospice is obligated to pay the physician or NP for the services.

We allow hospices to contract with another hospice to serve their patients, and would allow a hospice to arrange with another hospice to use its physicians to have the required face-to-face encounter. Likewise, hospices can contract with physicians for the purpose of having face-to-face encounters with their patients, but as previously noted, the contracted physician must then be the same physician who composes the narrative and signs the certification. Hospice physicians and NPs can be full-time, part-time, or work on a per diem. Hospice physicians and NPs are not required to have certification in hospice and palliative care.

NPs providing the face-to-face visit must meet Medicare's general qualifications for a NP and must be licensed as NPs by the State in which they are practicing. Physicians must meet the existing requirements for physicians in section 1861(r) of the Act. They must meet all State and local requirements as required in § 418.116. Finally, they must meet the licensed professional requirements at § 418.62.

If physicians employed by RHCs or FQHCs are also employed by or working under arrangement with a hospice, they could have the required face-to-face encounter, however they must follow statutory and regulatory requirements in doing so.

In summary, we are defining "hospice physician" as a physician employed by the hospice or working under arrangement with, or under contract with, the hospice. A hospice NP would be a NP employed by the hospice.

Comment: Several commenters asked if the encounter could be done using telephone or video technology, and still meet regulatory requirements. A few suggested that a nurse could be present to do the physical examination under the direct supervision of the physician, who could still see the patient and interact with him or her. Commenters suggested such an approach would be less burdensome and less costly, accomplish the same objectives, and open the door for critical but cost effective physician care to underserved or rural areas. Commenters were concerned about lack of human resources to accomplish the visit, particularly in rural areas, where driving distances can be great, increasing the cost of visits, and where there can be shortages of physicians or NPs. A commenter wrote that allowing telehealth would be consistent with the objectives of health care reform, and would offset travel time and travel costs. A few commenters noted that if telehealth were available, it would not help them due to lack of proper communication infrastructure in some remote areas; others noted that they would be willing to invest in telehealth to counterbalance the cost of sending a physician on home visits.

Response: We appreciate the commenters' concerns about meeting the face-to-face requirements in rural areas, and their suggestions to consider telehealth. However, section 1834(m) of the Act does not include hospices as an originating site for telehealth. Therefore, hospice patients would have to go to an originating site for the face-to-face encounter. In our analysis of claims data, we found that only 2.9 percent patients who would require a face-to-face encounter are in rural areas. Given this small volume of patients, we believe that not having telehealth does not hamper hospices' ability to meet the Affordable Care Act requirements; however, we will continue to monitor this for any unintended consequences.

Comment: A commenter wrote that in her hospice, the Medical Director would perform the face-to-face encounter and write the physician narrative. This commenter and others asked if the narrative and the face-to-face attestation could be combined; one asked if the visit note could serve in place of the narrative when the attending performs both functions. Several commenters suggested the face-to-face requirements were partially duplicative of the narrative. One notes that physicians are used to judging a patient's condition based on records. Other commenters asked for clarification of the differences between the face-to-face attestation and the physician narrative, and about the format, wording, and location of the attestation, and about how notes for the face-to-face encounter should be entered in the chart; a few asked for consistent guidelines for the narrative and the face-to-face attestation. One commenter asked if the same physician is responsible for both the visit and the narrative, could the recertification visit documentation form be combined with the recertification of terminal illness brief narrative form with both attestations so that the physician does

not have to dictate two separate notes and sign two separate forms.

A few commenters asked if the certification narrative and the face-to-face may be performed by more than one individual, or if hospice physicians could cover for each other. A commenter asked why a NP would provide an attestation of the face-to-face in addition to the physician. One commenter wrote that the face-to-face attestation should be a separate and distinct section of the narrative, and that providers should use an addendum form for the face-to-face attestation if the NP or a different physician from the certifying physician has the encounter. Another commenter asked if the NP could prepare the narrative and have the physician sign off on it. A few asked if electronic signatures were permitted for the attestation, narrative, and/or certification or if the face-to-face attestation could be dictated. One asked if a medically necessary visit is made within the same timeframe (proposed at 15 days), could the visit documentation serve as the narrative requirement, or would a separate narrative note be necessary. This commenter also asked whether it was a problem if the date of the visit did not coincide with the date of the attestation.

A commenter asked that the attestation also include the National Provider Identifier (NPI) of the physician or NP making the visit, to increase accountability. Another commenter asked us to clarify what goes directly above the certification signature—the narrative or the face-to-face attestation. Other commenters asked that the narrative attestation be placed above the physician's signature attesting that he/she composed the narrative based on his/her review of the medical record, or if applicable, his or her examination of the patient. Another commenter asked for guidance regarding the validity of the narrative if a clerical mistake is made in recording benefit period dates or certification dates. This same commenter noted that if his hospice uses contracted physicians or NPs to make the required face-to-face visits, these practitioners will be less familiar with the patient's history and disease progression, and stated that the narrative has the potential to be more informative about the patient's eligibility than the visit.

Another commenter asked if separate documentation would be required for any billable services provided during the visit, or could the narrative serve as the documentation. This commenter also asked what the documentation requirements for this visit would be. Several asked if there would need to be separate notes for the face-to-face encounter versus any billable portion of the visit.

A commenter wrote that attesting that an encounter has occurred and that documentation has been relayed does not confirm that the information was utilized in confirming eligibility. This commenter believes that the responsibility for verifying that all eligibility requirements have been met should remain with the certifying physician and be included in a single attestation.

A few commenters wrote that the additional attestation required for the face-to-face encounter creates an additional paperwork burden, and creates issues with forms, transcribing, timely documentation, and software updates. One commenter wrote that the final implementation date should be delayed to allow time for providers to update electronic and paper forms. A different commenter believed that it was burdensome, redundant, and unnecessary to require a physician or NP to attest in writing to having had a face-to-face encounter, and reiterated that the responsibility for verifying that the patient meets all eligibility criteria should remain with the physician and be included in a single attestation.

Response: The face-to-face requirement was added to the requirements for physician recertifications. Those requirements are described in detail in our regulations at § 418.22. In brief, currently hospices provide a signed certification or recertification which:

- States that the patient is terminally ill, with a prognosis of 6 months or less if the illness runs its normal course;
- Includes a written narrative either immediately prior to the physician's signature, or as a signed addendum. The narrative includes a statement under the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his or her examination of the patient; and,
- Is accompanied by clinical information or other documentation supporting the diagnosis.

The Affordable Care Act added a fourth component to the certification, with the face-to-face encounter and its attestation that the visit occurred. We proposed that the face-to-face attestation and signature be either a separate and distinct area on the recertification form, or a separate and distinct addendum to the recertification form, that is easily identifiable and clearly titled. We also proposed that the attestation language be located directly above the physician or NP attestation signature and date line.

Like the physician narrative, the face-to-face requirement is designed to increase physician accountability in the certification process, and to ensure that beneficiaries are eligible for the hospice benefit. While the purposes of the narrative and the face-to-face visit are similar, we do not believe that the two are duplicative of each other. There is value in having a physician see a patient, rather than just reviewing medical records about that patient, in determining continued eligibility.

The face-to-face attestation is a statement from the certifying physician or the NP which attests that he or she had a face-to-face encounter with the patient; if a NP had the encounter, the attestation should also state that the clinical findings of that encounter have been provided to the certifying physician for use in determining continued eligibility for hospice care. Unlike the narrative, the face-to-face attestation does not detail the clinical findings of the visit, but simply attests that the visit occurred. The regulations describing the narrative require that it be composed by the certifying physician, therefore a NP could not prepare it. We agree with the commenter who suggested that including the NPI of the individual who visited the patient increases accountability and we will consider including the NPI the face-to-face attestion in the future. We do not want to prescribe language that hospices should use in preparing the face-to-face attestation, provided the attestation includes the elements we have described.

The face-to-face attestation statement includes the date of the visit, and the signature of the physician or NP who made the visit, along with the date signed.

The date of the face-to-face encounter does not have to match the date that the attestation was signed; however, both dates should be included.

Several commenters asked if the narrative could be combined with the face-to-face attestation. The face-to-face encounter can be conducted by either a hospice physician who completes the certification, or a NP, and the face-to-face attestation must be signed by the person who conducted the visit. The narrative must be composed by the certifying physician, who by signing, attests that he or she composed it based on his or her review of the medical records and on examination of the patient (if any). We are clarifying that if a physician is the clinician who has the face-to-face encounter, then the same

physician should compose the narrative and sign the recertification.

The hospice has the option of putting both the face-to-face attestation and the narrative, with its accompanying attestation and signature, on the same page of the recertification. We would require that the format be such that the face-to-face attestation appears separate and distinct from the narrative and its attestation; hospices are free to decide how to separate the sections (that is, through spacing, through lines, etc.). We agree that for consistency, the narrative and its accompanying attestation should be above the physician's signature, and the face-to-face attestation should be above its accompanying signature, and are changing the regulatory text to reflect this. If the narrative and its attestation and the face-to-face attestation are included as part of the certification (rather than as an addendum), we suggest, but do not require, the order of the content to appear as follows: The face-to-face attestation (if applicable), followed by the physician narrative, followed by a narrative attestation, followed by the physician signature. We believe this order is logical as it allows the narrative attestation signature to be the same as the certification or recertification signature for those hospices which include the face-to-face attestation and narrative as part of the main certification document.

Hospices also have the option of placing the face-to-face attestation, the physician's or NP's signature, the narrative, and its attestation and signature, on a single page as an addendum to the main certification or recertification. They may also have the face-to-face attestation and narrative on separate pages as addenda to the certification and recertification documents. Finally, hospices may also include either the face-to-face attestation or the narrative in the main certification document, and have the other as an addendum. We are seeking to give hospices greater flexibility in how they include this information as part of their recertifications.

In summary, the narrative and face-to-face attestation may be included in the main certification document, but should be separate sections. They may also be on a single page as part of the main certification or recertification document, or as an addendum. The face-to-face attestation is completed by the person who visited the patient: either a hospice physician or a NP. If a NP saw the patient and completed the face-to-face attestation, the physician should not also complete the face-to-face attestation, because the physician did not make the visit. However, a certifying physician would still have to compose the narrative, using clinical findings from any face-to-face visit, and sign the narrative attestation.

We agree that attesting that an encounter has occurred and that documentation has been relayed does not confirm that the information was utilized in confirming eligibility. That is why we require hospice physicians to use the information from the face-to-face encounter in composing the narrative. We cannot combine the narrative and the face-to-face attestations into a single attestation because the statute allows NPs to perform face-to-face visits, but NPs cannot compose or sign the narrative.

The face-to-face encounter must be documented in accordance with hospice policy using currently accepted standards of practice. The documentation from the face-to-face encounter is part of the clinical record, and should be used in composing the written narrative. It is not necessary for the physician or NP to make separate notes for any billable services provided, as long as the visit documentation clearly supports any billable services that were provided. Visit notes are not a substitute for a physician narrative, which is a brief explanation of the clinical findings that supports continuing eligibility for the hospice benefit; the narrative draws on information from a variety of sources, and not just from notes of any face-to-face encounter which occurs.

While the mandated face-to-face attestation does create additional paperwork for hospices, we believe that we have provided sufficient flexibility for providers to meet the requirement. We appreciate hospices' concerns about required software changes and the timing required to make those changes. As noted earlier and again later in this final rule, our timeframe was driven by the required implementation date set by the Affordable Care Act, which was enacted in late March 2010. The statute requires implementation as of January 1, 2011; thus, it does not provide flexibility with respect to the date of implementation.

Electronic signatures are permitted on hospice certifications and recertifications; the narrative and the face-to-face attestation are parts of the certification or recertification, and therefore may also be signed electronically. If a physician forgets to date the certification, our longstanding policy described in our benefit policy manual in section 20.1 (Internet only manual 100–02, chapter 9) states, "If the physician forgets to date the certification, a notarized statement or some other acceptable documentation can be obtained to verify when the certification was obtained." The certification or recertification applies to the benefit period dates noted on the document, therefore, if those dates are recorded incorrectly, the hospice could potentially have days of service denied for coverage during a medical review.

Comment: A few commenters asked how the recertification visits relate to the local coverage determinations (LCDs). One commenter wrote that her hospice already completes guidelines from the LCDs for recertification, but much of this information requires prior knowledge of the patient condition to determine deterioration. The commenter noted that if the expectation is that the physician will be verifying the patient's condition based on the LCDs, this should be clear. The commenter was concerned about the situation where a physician or NP visits the patient, documents clear and valid reasons for recertification, but subsequent review determines the patient is not eligible based simply on lack of certain measures of decline. A few commenters asked us to provide clear guidance on what the face-to-face encounter should include (that is, elements that make up an encounter) for purposes of satisfying the requirement.

One commenter asked how a hospice should handle a situation where the physician determines the patient is no longer hospice eligible and discharges him, but the Quality Improvement Organization (QIO) finds the patient is hospice appropriate. The commenter wrote that it could not admit the patient in good conscience and asked for guidance.

Another commenter stated that he hoped that CMS is funding research to improve LCDs, saying that there is no formula for predicting "six months or less," especially for non-cancer diagnoses.

Response: In general, the face-to-face encounter for recertification requires that the same clinical standards be met as for the initial certification. The face-to-face encounter enables the clinician to assess the signs and symptoms in relation to the patient's terminal illness to determine whether the patient meets the clinical standards for recertification. When assessing the patient for hospice recertification, the medical records in addition to the face-to-face examination are utilized to provide a rationale for recertification. The clinical findings should include evidence from the three following categories:

(1) Decline in clinical status guidelines (for example, decline in

systolic blood pressure to below 90 or progressive postural hypotension);

(2) Non disease-specific base guidelines (that is, decline in functional status) as demonstrated by Karnofsky Performance Status or Palliative Performance Score and dependence in two or more activities of daily living; and

(3) Co-morbidities. For more information about the criteria, please see local coverage determinations (L13653, L25678, or L29881). These LCDs are on the CMS Web site in the Medicare Coverage Database at *http://www.cms.gov/mcd/overview.asp.* They are also on the local contractors' Web pages.

Predicting life expectancy is not an exact science. We are not currently funding research related to LCDs; research that could inform LCDs is completed through a number of venues, including academic institutions, the private sector, and some government agencies. In determining life expectancy for conditions with less predictable trajectories, hospice physicians are also free to use any disease-specific scores or scales that can help them in predicting life expectancy. Some providers already do so, and have reported that it improves the accuracy of their prognoses.

If a patient improves or stabilizes sufficiently over time while in hospice, such that he/she no longer has a prognosis of 6 months or less from the most recent recertification evaluation or definitive interim evaluation, that patient should be considered for discharge from the Medicare hospice benefit. Such patients can be reenrolled for a new benefit period when a decline in their clinical status is such that their life expectancy is again 6 months or less. Conversely, patients in the terminal stage of their illness, who originally qualify for the Medicare hospice benefit but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than 6 months, remain eligible for hospice care.

A patient's condition may temporarily improve with hospice care. When improvement is evident in documentation such as physician orders, medications, hospital records, doctor's records, other health records, test reports, etc, contractors consider the length-of-stay and the length of sustained improvement.

There should be clear evidence of the status of the patient's conditions and the clinical factors that caused the patient to be not eligible or to be recertified as terminally ill. If the patient is recertified, the medical records should reflect the length of time the symptoms have been evident, evidence of progressive deterioration or sudden deterioration, and increase in frequency and intensity of hospice services and medications.

If a patient appeals a pending discharge to the QIO, the QIO decision is binding; a hospice could not discharge a patient as ineligible if the QIO deems that patient to be eligible. The provider is required to continue to provide services for the patient. In the QIO response, the QIO should advise the provider as to why it disagrees with the hospice, which should help the provider to re-evaluate the discharge decision. If at another point in time the hospice believes that the patient is no longer hospice eligible, the provider should give timely notice to the patient of its decision to discharge. The patient could again appeal to the QIO, and the hospice and patient would await a new determination from the QIO based on the situation at that time.

Comment: A number of commenters were concerned that the required face-to-face encounter would create access problems for patients, would delay care and thereby lead to unnecessary patient suffering, or would reduce the quality of patient care. One commenter wrote that doctors may be less willing to refer patients to hospice if required to have these encounters, while others were concerned that patients would be discharged; several suggested that the face-to-face requirement could lead to overall Medicare costs increasing as these patients use emergency rooms and inpatient services at end-of-life rather than hospice. Several commenters were concerned that those who were actively dying would have care delayed if they required a visit upon admission due to previous hospice stays, as the hospice may have to wait to get a hospice physician or NP to see the patient.

Some commenters wrote that access to hospice services may be limited for patients who live in outlying areas, because of the travel time required to make the visits. Another commenter wrote that lack of transport to bring rural patients to a physician would lead to denying access to care for many elderly or bedbound patients unable to have a timely face-to-face visit. A few commenters suggested they may have to reduce their service areas to meet the requirement, which would jeopardize access to hospice services for beneficiaries in outlying areas. Another commenter believed that with staff shortages, meeting the face-to-face requirement would require the hospice to pull practitioners from patients who need the care and expertise of a physician or a NP to make required visits. The commenter believed this would reduce services and lower the quality of care that patients receive. A few commenters wrote that the requirement could lead to patient discharge, with one noting that the subsequent hospice would then have to incur the cost of the required visit. One commenter wrote that discharging patients could lead to ethical dilemmas or charges of patient abandonment. A few commenters suggested that the result of this mandate would be increased cost to the health care system if long-stay patients are discharged from hospice care. One commenter asked what options would be available to a hospice, or to the patients, if agencies in medically underserved areas are unable to locate physicians or NPs who are able and willing to make the required face-to-face visits.

A few commenters said that volunteer Medical Directors used by rural providers cannot make these visits, which would force the hospice to discharge patients. Another commenter said that with the maturation of the baby boomer generation, demand for hospice services would be rising, at the same time that fewer qualified physicians are pursuing careers in gerontology or palliative care, and believes that this would intensify the current situation. Another commenter wrote that it is in his agency's best interest to have physicians certified in hospice and palliative care to make the visits, but that recent requirements for an internship mean these physicians will be in shorter supply, and therefore, more costly to hospices.

A few commenters were concerned that hospice programs may not be able to manage this burden, and their closure would affect vitally important access to hospice services. One wrote that the data collected by the Community Hospice Partnership, a national coalition researching the economic sustainability of not-for-profit hospices, estimates that the cumulative reductions in reimbursement would lead to closure of 65 percent of Wisconsin's rural hospices by 2014. The commenter added that this proposed face-to-face requirement was not considered in the analysis, meaning rural Wisconsin providers would be more severely affected.

Response: We appreciate the commenters' concern about the timeliness and quality of patient care and about patient access to hospice services. We believe that this provision was included in the Affordable Care Act to ensure the continued eligibility of

hospice patients, who are supposed to have a life expectancy of 6 months or less. MedPAC, the OIG, and CMS have concerns about the appropriateness of some long-stay patients, who may have been admitted to hospice care too early in the course of their illness. The hospice face-to-face encounter is only required for recertifications when the patient is in the 3rd benefit period or beyond, which is after 6 months of hospice care for those who complete each benefit period. As mentioned previously, we found that only 2.9 percent of all Medicare hospice beneficiaries were in the 3rd or later benefit period and in rural areas, where physician or NP shortages are greatest. Therefore, only a small percentage of all Medicare hospice patients will both require these encounters and will be in a rural area where physician is more of a concern.

With that perspective, we believe that physicians will not hesitate to refer appropriate patients to hospice. We clarify, for the commenter, that it is the responsibility of the hospice to ensure that the face-to-face encounter occurs. We do not allow outside attending physicians to have the face-to-face encounter, and the hospice is responsible for either providing the encounter itself or for arranging for the encounter. Therefore, we do not believe that physicians will reduce referrals inappropriately, leading to unnecessary suffering and increased Medicare costs for patients at end-of-life. As noted in a previous comment, a patient may require a visit at admission and be actively dying. In this situation, a hospice physician or NP might see the patient anyway, given the circumstances cited; hospices are supposed to provide physician services to their patients when needed during a time of crisis. Our data suggest that only 1.1 percent of hospice beneficiaries live in rural areas and require a face-to-face encounter at admission. Therefore, we believe this is an infrequent situation, which will not lead to delays in care or in the admission of the patient.

While we appreciate the additional training and experience of those physicians who specialize in gerontology or in palliative care, we do not require a hospice physician or NP to be certified in those specialties. Volunteer physicians are considered hospice employees, and are permitted to have face-to-face encounters with patients. As previously noted, we also are allowing hospices to bill for any medically reasonable and necessary patient care provided by a hospice physician, or by a hospice NP who is also the patient's attending physician, in the course of a face-to-face visit. Therefore, hospices will receive some financial relief for the costs of having these required visits, and should not experience the financial burden some commenters described.

As noted previously, we have also doubled the time allowed for making a required visit to 30 calendar days prior to the recertification date to better enable hospices to meet this requirement. Given the additional time for having face-to-face encounters, we do not believe that hospices will need to discharge patients due to lack of time to complete the face-to-face encounters, which could result in increases in non-hospice healthcare costs or which may raise ethical issues. Similarly, if a hospice physician or attending NP cannot travel to the patient for the required visit due to distance, time, or other reasons, and the hospice is encountering a shortage of physicians or NPs such that it cannot find any to hire or any physicians to contract with, the hospice can have the patient come to the physician or NP for the face-to-face encounter, provided the hospice meets the requirements in the CoPs regarding patient safety and comfort. Having the patient come to the physician or NP, when appropriate, can also be considered if a hospice is concerned that using its staff to make required face-to-face visits would reduce services or lead to lower quality patient care. We believe that requiring a face-to-face encounter with a hospice physician or nurse practitioner will lead to increased quality of care for hospice patients, rather than decreasing quality of care.

We are unable to comment on the data collected by the Community Hospice Partnership, or their findings, as we do not have those data, the study methods, or findings, however, the reimbursement allowed to hospices for providing reasonable and necessary patient care in the course of a required face-to-face encounter should provide financial relief to providers.

Comment: Several comments suggested alternative approaches to the face-to-face encounter to ensure continued hospice eligibility. One commenter suggested that hospices can better manage their patients by performing an automatic chart review for long-stay patients, and include better prognostication information on their recertifications. This commenter also wrote that her hospice is researching using validated prognostication tools which are disease specific, and which can be done by a RN just as effectively as by a physician. A different commenter wrote that his hospice uses a detailed review process for patients not showing decline, and is therefore already performing what the proposed rule is trying to accomplish. This commenter suggested that we initially enforce the face-to-face requirements for all hospices but allow those providers that have a lower rate of long-stay patients to "opt out" in the future. The commenter believes this would force hospices to focus on admission practices and not place an undue burden on responsible providers. Another commenter wrote that his hospice's Discharge Management process is redundant in relation to the face-to-face requirement, and asked that we eliminate it. Another suggested that we require a separate comprehensive assessment for long-stay patients.

One commenter wrote that it seemed like her hospice was being punished because a lack of Federal oversight has allowed some hospice programs to go astray. Several commenters understand the need to combat fraud and abuse; one also suggested that uncontrolled growth in the number of providers, vulnerabilities in the payment systems, and a diminished commitment to integrity by some newer providers was at the core of the problem, and led to ill-conceived regulatory changes. These commenters suggested that better enforcement of existing regulations, closer inspection of documentation through ADRs/medical review, review by recovery audit contractors, comprehensive error rate testing audits, Medicaid program integrity audits, zone program integrity audits, OIG investigations, more frequent surveys, and/or other interagency efforts to combat Medicare fraud would be a better approach. One commenter suggested that if we are concerned about the growth of hospice, we should implement a moratorium on new hospice providers for 5 years, where no new hospices could enter a market unless an existing hospice in that same area closes. A few commenters wrote that they believe the cap reimbursement mechanism is the best control of utilization rather than "Monday morning quarterbacking prognosis" or seeking confirmation of prognosis by a visit by a physician or other practitioner.

A few suggested we delay or suspend implementation (often suggesting a delay until January or February 2012), or eliminate the requirement altogether. One commenter asked that if we decide to delay implementation, we notify the industry immediately, rather than waiting for publication of the final rule, so that hospices could effectively plan their staffing and hiring. Another noted that hospices have not been allowed

adequate time in practice to determine the increased level of physician involvement to meet this requirement. One wrote that we should eliminate the face-to-face visit prior to readmission, if the two physicians agree to the certification of terminal illness. Another commenter suggested we only require a face-to-face encounter if the Medical Director has not made a visit within the recertification period for other medical issues.

Several suggested that we only require the face-to-face for hospices that have a higher than average length of stay, or that we apply the requirement to patients with stays greater than 240 days. Other commenters suggested we waive the requirement for hospices that tend not to enroll very long-stay patients, or for small and rural hospices with less than a 25–50 person daily census, or for all rural hospices. Another commenter suggested we exempt patients and providers in Health Professional Shortage Areas from the requirement. One commenter suggested that we only apply this mandate to continuous service greater than 180 days with no break in service. A few suggested we require the visit at 180-days but only at every other or every third recertification thereafter, or every 180 days thereafter; another suggested we not require the visit at the benefit periods after 180 days until the total effects of the mandate have been evaluated. Some suggested a phased or stepped approach to implementation, such as applying it to hospices with a high proportion of long-stay patients first. Another suggested 100 percent review of patient stays over 180 days in providers with an unusually high percentage of "long-stay" patients. This commenter wrote that this would be a welcome edit targeted at problem providers.

The same commenter also suggested that the face-to-face encounter be crafted around the provider and not the patient, with the encounter required prior to the 180th day of care within a provider, rather than over the patient's entire hospice history, with subsequent visits required again at each 180-day interval within that provider. This commenter suggested that if the patient transfers or is later admitted to another hospice, the 180-day count would start over. To avoid having unscrupulous providers that own other provider numbers in the same geographic area make patient transfers designed to dodge the visit requirement, the commenter suggested we could have a 100 percent review of long-stay providers, using an edit of chain-related providers.

Another commenter suggested that if there was greater than a 3- or 6-month hiatus between hospice admissions, the mandate should not apply to the total hospice stay, but instead would start with the subsequent hospice admission.

Other commenters suggested that the hospice Medical Director could meet the requirement with a phone consultation with the patient while a hospice nurse was seeing the patient, at the time of the recertification visit. Another commenter believes that since the patient is reviewed by the hospice team at least every 14 days, a physician is already certifying his/her belief that the patient is indeed eligible. Others wrote that hospice nurses are trained in recognizing and documenting the appropriateness of patients, and are familiar with the patients' history. These commenters stated the requirement was an unnecessary burden on hospices since nurses are adequately handling this now, and could communicate with the physician regarding the continued need for care and recertification.

Some commenters were concerned that the impact of the narrative requirement from the August 6, 2009 FY 2010 hospice wage index final rule (74 FR 39384) was not yet known, and were concerned about the effect of the face-to-face requirement on rural providers. One suggested we conduct studies first to determine the effectiveness of the narrative before requiring the face-to-face encounter. Others suggested that we waive the requirement in areas of documented physician shortages, and others suggested that we waive the requirement for patients that require a face-to-face encounter at admission and who die within a week or who are imminently terminal.

Response: We agree with the commenter who suggested that providers can improve their patient management by performing automatic chart reviews or other review processes for long-stay patients. We also encourage hospices to consider using validated prognostication tools, when available, to inform the larger process of estimating life expectancy.

We agree that preventing fraud and abuse is important; Medicare and other agencies continue in their efforts to identify providers who are abusing the hospice benefit. We also agree that the hospice aggregate cap is an effective means of controlling inappropriate utilization. We believe that while both fraud and abuse prevention and the aggregate cap are helpful in preventing inappropriately long stays, they are not the only means to do so. The face-to-face requirement should reduce inappropriately long stays as physician accountability in the recertification process increases. In the effort to prevent fraud and abuse, the aggregate cap and the face-to-face encounter are complementary approaches to dealing with abuses in the hospice benefit.

A few commenters suggested targeted medical reviews, and the Affordable Care Act also requires medical reviews of certain long-stay cases.

State governments, not the Federal Government, control whether to place a moratorium on new providers, so that comment is outside of our purview.

In its 2009 *Report to Congress,* MedPAC reported that a panel of hospice experts agreed that more physician accountability was needed in the certification and recertification process (Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy,* Chapter 6, March 2009, pg 365, available at *http://www.medpac.gov/documents/Mar09_EntireReport.pdf*). The panelists' comments were part of the impetus for MedPAC's recommending the face-to-face encounter that the Congress enacted in the Affordable Care Act. Requiring another comprehensive assessment for long-stay patients would shift the burden of gathering information to ensure eligibility from physicians back to RNs and other staff, which would defeat the purpose of the MedPAC recommendation and would not follow the statutory language. Allowing a physician to speak by phone with the nurse while he or she is present with the patient is not a face-to-face encounter as required by the law.

Section 3132(b)(2) states that the face-to-face encounter is effective beginning on January 1, 2011. The statute is clear and we have no discretion to delay, phase-in, or suspend implementation, regardless of the type of hospice (*e.g.,* rural, those with small censuses, those in areas of physician shortages) or for any other reason (other than a change in law). Nor can we apply the mandate to select situations, such as to patients with more than 180 days of continuous service, to patients who haven't seen the medical director for another reason within the recertification period. We also cannot allow some providers to "opt-out" of the requirement after a period of time, nor can we limit the requirement to those hospices with a higher percentage of long-stay patients, or to those patients where two physicians agree to the recertification. We cannot craft the timeframe for the face-to-face encounter around the provider, as the statutory language is explicit in requiring it at certain benefit periods. Benefit periods are counted

based upon a patient's total Medicare hospice history, rather than a patient's hospice history with a given provider. We cannot deviate from the statutory language which specifies when the face-to-face encounter must occur ("prior to the 180th-day recertification and each subsequent recertification"). We will continue to monitor the data for any unintended consequences from the physician narrative or from the hospice face-to-face requirement.

Comment: A few commenters asked if hospices would be expected to perform a face-to-face encounter in December 2010 for patients who will require a face-to-face encounter during January 2011. One asked that we "grandfather" in patients whose recertification would require a face-to-face visit in January 2011. Others asked that the requirement only be effective for patients admitted to hospice on or after January 1, 2011 rather than including patients who were admitted prior to January 1, 2011, and whose stays crossed into 2011. One commenter wrote that this would allow hospices to marshal the necessary personnel and training resources, to create systems, and to minimize disruption in patient care.

Response: In implementing the hospice face-to-face requirement, we must follow the relevant statutory language in the Affordable Care Act, which says, "a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification * * *".

The language does not require hospices to have a face-to-face encounter with existing patients who entered the 3rd or later benefit period in 2010, and were recertified in 2010. It does require that patients who enter the 3rd or later benefit period in 2011 have the face-to-face encounter; the statutory language does not give us flexibility to "grandfather" in existing patients. We also believe that by extending the timeframe for the face-to-face encounter from 15 to 30 calendar days, hospices will have the flexibility to meet this requirement for patients who will enter the 3rd or later benefit periods in 2011.

Comment: A commenter stated that she is not aware of any data indicating that a physician who sees a patient in a face-to-face encounter once in a 6-month period is better able to prognosticate than a skilled hospice nurse who has seen the patient serially over a 6-month timeframe. The commenter added that unless the physician's one time face-to-face assessment results in a more accurate prognosis, this requirement is of very questionable value in the efforts to improve the process. Another commenter wrote that the additional burden from the visit does not support a face-to-face encounter; one wrote that those who provide care ethically and in compliance with regulations would have an additional paperwork burden, but this will not effectively eliminate the unethical providers. Another commenter wrote that it would be extremely cumbersome to develop processes in-house with electronic records and software to meet the face-to-face requirements. One commenter wrote that the proposal goes beyond the mandates of the Affordable Care Act in proposing additional layers of payment cuts on top of the disproportionate cuts already scheduled for hospice.

Another commenter said that it is not always feasible, practical, or efficient to require face-to-face encounters as proposed. A commenter believed that the attestation and narrative requirement already created a burden greater than the benefit for physicians, patients, and agencies, and that this additional face-to-face requirement would serve as a further barrier to care in areas where patients are already underserved, an economic hardship for small nonprofit providers, and would ultimately result in decreased quality of care for patients and increased costs to Medicare through unnecessary testing, procedures, hospitalizations, and readmissions. A commenter wrote that this face-to-face encounter requirement would lead to decreased utilization of hospice services, decreases lengths of stay if hospices discharge patients too soon, which may diminish the purpose of hospice and mute its services. Other commenters wrote that requiring a face-to-face visit by a physician or NP adds a layer of complexity not only to the hospice, but also to the patient's routine, due to travel, location, and additional paperwork without any compensatory benefit. One commenter wrote that this new requirement does little to truly benefit the patient or to protect the hospice benefit from abuse. Another wrote that patients in small rural communities would be inconvenienced because of the fraudulent behavior of large for-profit hospices.

Response: We appreciate the commenters' thoughts on the value of the face-to-face encounter. We are taking a long-term view of the encounter, and expect that it will increase physician accountability, lead to discharge of ineligible beneficiaries thereby reducing some lengths of stay, and improve the quality of patient care. While we value the hospice nurse's experience with the patient, and his or her assessment of the patient's prognosis, we believe that face-to-face encounters with hospice physicians or NPs can only improve upon that process.

We do not believe this requirement will decrease hospice utilization by eligible patients. We also do not claim that by itself, this requirement will eliminate all abuse of the hospice benefit. As noted previously in this section, this mandate complements other efforts related to protecting the hospice benefit from fraud and abuse.

This requirement does not cut payments, nor do we believe it is overly burdensome. We have provided financial relief for the cost of the visits by allowing billing of reasonable and necessary patient care by the hospice physician or hospice attending NP that occurs during a required face-to-face encounter. We have also provided additional flexibility in the timing of visits, to assist rural providers. We believe these changes help ensure that this requirement does not serve as a barrier to care in underserved area, and will monitor for any unintended consequences.

While changes in certification requirements may lead to additional paperwork or to software changes, we do not believe that these will be burdensome or overwhelming; rather they are a routine cost of doing business. We have also provided hospices with great flexibility in how they include the face-to-face attestation as part of their recertification documents. We agree that the allowable timeframe for making changes to software or to electronic records is short, and have addressed these concerns later in this section.

We believe that in the long-term, it will strengthen the hospice benefit by returning it to the benefit the Congress intended, for patients who are terminally ill with 6 months or less to live. We are concerned that the hospice benefit is being used by some providers to care for chronically ill patients rather than terminally ill patients, or to serve as a long-term care benefit. We believe that this face-to-face requirement may help to ensure the continued viability of Medicare's hospice benefit for those at end-of-life.

Comment: A number of commenters wrote to support the intent of the rule to certify only those hospice patients who remain eligible for the hospice benefit or to increase physician accountability, though a few mentioned that those who abuse the benefit would find a way to circumvent the requirement or that the proposed rule

was too stringent. One wrote that it is a wise way to counter the growing use of hospice services by those who are chronically ill, rather than terminally ill. Another commenter values the sort of practice, which was proposed as it ties the persons of the treatment team with the patient and with the family. A few commenters also supported our proposal that a certification or recertification could be completed 15 days prior to the start of the benefit period. A commenter from a non-profit hospice wrote that the Congress' and CMS' faith in the value of physician certification to halt abuse was reasonable, and was important for the nonprofit hospice community to support.

Response: We thank the commenters for their support.

Comment: A commenter was concerned that the timing of the proposed rule, with the open comment period until September 14th and a final rule not due out until late October or mid-November, puts a considerable burden on providers and their patient management software companies. The commenter wrote that software changes would need to be made based on the proposed rule, and that her software company could not beta test its changes because there is not enough time to do so, and to get the software out in November. The commenter added that any changes CMS makes between the proposed and final rules are difficult to accommodate, but obviously necessary. The commenter believes that in the future it would be more reasonable for CMS to publish proposed rules with adequate time for comments, review, and a final rule to be published several months before the effective date, so that software companies and their clients would have adequate time to prepare for the changes. The commenter added that due to the number of unresolved issues with the face-to-face proposal, the regulation effective date may be delayed which would also impact the timing of hiring of additional staff. A few commenters wrote that the timeframe, from publication of the final rule to its effective date, means that hospices have little time to meet with current physician staff to determine if they can manage the required visits, and to hire and train additional physicians and NPs if needed; several asked for more time to hire and train additional staff.

Response: The hospice face-to-face requirement was included in the Affordable Care Act, which was enacted on March 23, 2010. Conforming amendments were added to that law on March 30, 2010. We typically publish hospice payment-related proposed rules in April and final rules in late July or early August. Because of the internal process to publish a proposed rule by the end of March and the date the Affordable Care Act was signed into law, it was too late to include the provisions related to the face-to-face requirement in a hospice proposed rule. The most appropriate rulemaking publication we could use was the HH proposed and final rules. In addition, the HH payment rules have an effective date of January 1st while the hospice payment rules are effective on October 1st.

When we propose and finalize changes to policies, we try to do so with a timeframe that provides adequate time and flexibility to providers, contractors, and software vendors, to implement final rule requirements. In this case, the timing of the enactment of the Affordable Care Act led us to propose the requirements later than usual; the effective date of the face-to-face requirement is mandated in the statute, and we cannot change it. However, the timing of the proposed rule allowed for a 60 day public comment period and the final rule will be effective on January 1, 2011.

Comment: Some commenters asked if they were expected to report the required face-to-face visit on their claims. One wrote that if hospices are expected to report the visit, they should be paid for it. A commenter asked whether hospices should report the NP's NPI number on the claim or the NPI number of the physician supervising the NP. Several commenters asked if any special codes should be included on claims when the face-to-face visit is combined with a patient care visit, or when the face-to-face visit occurs during a medically necessary physician visit.

Response: We are not requiring any visit reporting for the required face-to-face encounter on hospice claims. This is consistent with our policy of not currently requiring reporting of other administrative activities on hospice claims. Hospice claims currently show the NPI of the attending physician (who may be a NP) and the certifying physician, at the claim level rather than showing the NPI of a practitioner at the line-item level. If hospice physicians or attending NPs provide billable services (as described previously in this section) during the course of the visit, those are to be billed on the claim following usual physician billing procedures, using revenue code 0657 and the appropriate CPT codes. If billable NP attending physician services are included on the claim, the claim should also include a GV modifier, since NP services are paid at 85 percent of services provided by physicians. The NP's NPI number would only be reported on the claim if the hospice NP is also the patient's attending physician.

Comment: A commenter wrote that hospice programs have raised concerns that hospice physicians or NPs may, during their visit to gather clinical findings to meet the face-to-face encounter requirement, be expected, by the patient or family members, to treat the patient for issues that are not related to the terminal diagnosis. The commenter noted that this is a particular concern in cases where the patient is not under the direct medical care of the hospice Medical Director but under the care of his or her primary care physician. The commenter suggested that CMS should acknowledge the potential for such professional/ethical conflicts and make every effort to avoid establishment of any barriers (either through hospice CoPs or coverage requirements) that would prevent the physician or NP from providing adequate notice or explanation to a patient or responsible family member regarding the purpose of the hospice face-to-face encounter.

Response: The hospice physician is responsible for providing care for the terminal illness and related conditions, and for caring for any unmet medical needs that the patient's attending physician (if any) has not addressed. If both the hospice physician and the attending physician are involved in the patient's care, the patient is taught who to consider "primary" and contact first. The hospice is to collaborate with the patient's attending physician (if any) in obtaining the initial certification, in performing the comprehensive assessment and any updates to that assessment, in developing the written plan of care, in discharging the patient, etc. Therefore, there should already be a working relationship with the patient's attending physician; in having a required face-to-face encounter, the physician or NP should coordinate with the attending physician in providing any care to the patient. Because the required face-to-face encounter is usually an expected event, the hospice has time for such coordination. If the hospice physician or attending NP provides reasonable and necessary patient care while making a required face-to-face visit, the hospice may bill for those non-administrative physician services, as described previously in this final rule.

Comment: A commenter wrote that CMS has provided no clarity regarding the hospice's exposure should the face-to-face requirement not be met.

Response: The face-to-face requirement is part of the hospice recertification process. Having a valid recertification is a statutory requirement for coverage and payment. We would have grounds to demand and recoup payments for claims that were paid based on an invalid recertification due to not satisfying the face-to-face requirement.

Comment: A commenter recommended that CMS continue to accept the hospice date stamp on POCs returned to the agency by physicians who forget or fail to date their signature on this document.

Response: At this time, there is nothing to preclude a hospice from using a date stamp if a physician fails to date his or her signature on the POC.

Comment: One commenter wrote that including the benefit period dates on the certification and recertification forms imposes a clerical task in physician charting. The commenter asked why this was proposed if the face-to-face encounter requirement is based upon actual days of care.

Response: As noted previously, the face-to-face encounter is based upon benefit periods and not on actual days of care. Therefore, it is helpful to show benefit periods on the certification. As we wrote in the proposed rule, having the benefit period dates on the certification makes it easier for the hospice to identify those benefit periods which require a face-to-face encounter, and will ease enforcement of this new statutory requirement. Additionally, including the benefit period dates on certifications or recertifications simplifies the medical review process. The physician does not have to be the one to fill in the benefit period dates, but he or she should know what period of time the document covers.

Comment: A commenter wrote that this rule was proposed as intended to be applied to hospices that routinely skew the length of stay averages with long lengths of stay and exceed the hospice caps. The commenter added that it is now applicable to every certified hospice regardless of appropriate lengths of stay or not.

Response: Our proposal is entirely based on section 3132(b) of the Affordable Care Act. The Affordable Care Act did not limit the face-to-face requirement to certain hospices, but required it of all certified hospices.

Comment: A commenter wrote that if CMS plans to reimburse the face-to-face visits, long term care (LTC) facilities should not be involved in hospice billing as the proposed rule is clearly focused on hospice operations, not those of the LTC that contracts with the hospice so patients may receive hospice services. The commenter asked that if CMS anticipates any increased responsibilities of LTC providers, that his organization be included in any stakeholder discussions. Finally, the commenter asked that we clarify that the role of LTC providers will not change under this new regulation.

Response: These requirements affect hospices only and do not affect or change the responsibilities of LTC providers that serve hospice patients who reside in their facilities.

Comment: A commenter asked if the new requirement for physician or NP face-to-face encounters replaces current RN assessments of hospice patients.

Response: This new requirement does not affect the roles and responsibilities of hospice nurses. Hospice nurses should continue to care for and assess patients in accordance with the CoPs. They should continue to provide care for the palliation and management of the terminal illness and related conditions.

Comment: A commenter asked if the new face-to-face requirement allowed the Medical Director to certify hospice patients. Several commenters urged that electronic signatures be accepted for certifications and recertifications or on the attestations. Another commenter asked if having a different diagnosis at admission would affect the face-to-face requirement.

Response: Hospice Medical Directors have always been able to certify or recertify hospice patients. Additionally, electronic signatures on certifications and recertifications continue to be allowed; the narrative and the face-to-face attestation are parts of the certification, and therefore both can be signed electronically. The new face-to-face requirement does not affect either of these policies. The face-to-face encounter is required based upon being in the 3rd or later benefit period, considering the entire hospice history, regardless of diagnosis.

Comment: A commenter wrote that if the face-to-face encounter must occur within 2 weeks of the start-of-care date, and be documented, the industry could not afford this. This commenter noted also that hospices have little or no influence over physician behavior to comply with the additional scheduling and documentation requirements of this proposed rule.

Response: We believe this comment is related to the HH face-to-face requirement, but it was unclear from the language used, so we will respond from a hospice perspective. The hospice face-to-face certification is not required at start-of-care unless, when considering the patient's entire hospice history, the start-of-care coincides with the recertification at the 3rd or later benefit period. If a hospice employs or contracts with a physician, it has influence regarding physician compliance with these requirements.

Comment: A commenter wrote that a recent Duke University study showed that patients who died under the care of hospice cost the Medicare program an average of $2,300 less than those who did not. This commenter believes that the current reimbursement model no longer fits with the evolution of the hospice benefit since 1983. The commenter also believes that this maturation of hospice necessitates a full scale review and evaluation of the current reimbursement model. The commenter added that changes to the benefit and payment system should preserve access the hospice benefit, quality care, and reasonable reimbursement rates to maintain a viable and stable delivery system. The commenter also wrote that hospice patients should not have to forgo curative care that might lengthen their lives and enhance their quality of life. This commenter also wrote that the Congress should prevent CMS from implementing payment rate cuts in hospice until the Secretary is able to justify that the cuts do not negatively impact patients and access to care. The commenter suggested that the Congress prevent us from implementing the payment rate to ensure the full market basket update for the hospice benefit, and that they preserve the BNAF; commenters suggested a rural add-on payment to ensure access for rural patients and to compensate for the financial burden of the face-to-face visits.

A few commenters who opposed the elimination of the BNAF wrote that we moved the hospice wage index away from one which was agreed upon years ago; one asked that we suspend the phase-out until a better approach for wage index adjustment is developed. Another commenter believes the hospice wage patterns do not mirror those of hospitals. This commenter wrote that hospices compete in the same labor market as hospitals, which are allowed to reclassify. The commenter urged us to develop a voluntary pilot project to test a hospice specific wage index, and hopes that we will slow the phase-out. A few commenters also urged that we maintain the aggregate hospice cap, as it protects against abuse of the benefit. One supported our efforts to improve the calculation and enforcement of the cap, provided those efforts do not take away from payment

reform. A different commenter suggested we have standards for data submitted on cost reports and not use data from agencies that submit reports that are missing required information.

Response: Some of these comments are outside the scope of this rule so we will not respond to them in this final rule. However, we will respond to those comments related to the Affordable Care Act. Section 3132(a) of the Affordable Care Act requires that we begin reforming the hospice payment system no earlier than October 1, 2013. We have been collecting additional data from hospices for several years now, in preparation for payment reform. Any reformed payment model that we propose would preserve access to hospice care, encourage quality care, and would fairly pay providers. Section 3140 of the Affordable Care Act requires that we conduct a concurrent care demonstration project where hospice services will be provided without the beneficiary having to forgo curative care. The results of this 3-year demonstration project will help inform future decisions about any changes to the hospice benefit. In the Affordable Care Act, the Congress also reduced the market basket update for hospice, but those reductions will not occur until 2013, and therefore are not included in the FY 2011 payment rates. We do not have the statutory authority to provide a rural add-on to hospices. The BNAF phase-out was finalized in the August 6, 2009 final rule, and is outside the scope of this rule. Likewise, the hospice wage index, cost reports, and cap are outside the scope of this rule, and therefore we cannot comment, though we appreciate the commenter's support regarding the hospice aggregate cap.

In summary, as a result of the comments we received on the proposed rule, we are finalizing the proposals made in the proposed rule with the following changes:

- We are changing the regulatory text at § 418.22(a)(4) to clarify that we are counting a beneficiary's time across all hospices based upon benefit periods rather than on actual days of hospice care. Therefore, a face-to-face encounter will be required prior to the 3rd benefit period recertification and each recertification thereafter.
- We are clarifying in the regulatory text at § 418.22(a)(4) that the hospice physician or nurse practitioner is not required to go to the patient for the face-to-face encounter, but that the patient is allowed to travel to the hospice physician or nurse practitioner when medically appropriate.
- We are changing the regulatory text at § 418.22(a)(4) so that hospice physicians or nurse practitioners will have up to 30 calendar days prior to the 3rd benefit period recertification, and up to 30 calendar days prior to each recertification thereafter, to have the face-to-face encounter.
- We are changing the regulatory text at § 418.22(b)(3)(iii) so that the narrative attestation is directly above physician's signature, rather than directly below it.
- We clarified that hospices may bill for reasonable and necessary care provided to the patient by a hospice physician in the course of having a required face-to-face encounter with a patient.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information (COI) requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Therapy Coverage Requirements

As described previously in this rule, we are clarifying our coverage requirements for skilled services provided by therapists, which are described in § 409.44(c). Our clarifications include requirements to: Document necessity for a course of therapy (§ 409.44(c)(1)); include clinic notes which reflect progress toward goals, which incorporate the functional assessment and reassessments, which justify medical necessity, which describe the content of progress notes, and which include objective evidence of the expectation that the patient's condition will improve (§ 409.44(c)(2)(i)); document any variable factors that influence the patient's condition or affect the patient's response to treatment, and include objective measurements of progress toward goals in the clinical record (409.44(c)(2)(iv)).

These clarifications to our coverage requirements in § 409.44(c) are already part of our current Conditions of Participation (CoPs) and are approved under OMB# 0938–1083. The current CoPs at § 484.12 already require that the HHA and its staff comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Those accepted professional standards include complete and effective documentation, such as we described in our proposals. Additionally, § 484.32 of the CoPs already requires in part that the therapist prepare clinical and progress notes. Section 484.55 of the CoPs already requires that HHAs provide a comprehensive assessment that "accurately reflects the patient's current health status and includes information that may be used to demonstrate progress toward achievement of desired outcomes". Because these clarifications to our coverage requirements in § 409.44(c) reflect longstanding policy from our CoPs as well as from accepted standards of clinical practice, we believe that these requirements will not create any additional burden on HHAs.

Additionally, our coverage regulations at § 409.44(c)(2)(i) already mandate that for therapy services to be covered in the HH setting, the services must be considered under accepted practice to be a specific, safe, and effective treatment for the beneficiary's condition. We are revising § 409.44(c)(2)(i) to require a functional assessment on the 13th and 19th therapy visit, and at least every 30 days, to determine continued need for therapy services, and to ensure material progress toward goals. The functional assessment does not require a special visit to the patient, but is conducted as part of a regularly scheduled therapy visit. Functional assessments are necessary to demonstrate progress (or the lack thereof) toward therapy goals, and are already part of accepted standards of clinical practice, which include assessing a patient's function on an ongoing basis as part of each visit.

Our current CoPs at § 484.55 already require that HHAs "identify the patient's continuing need for home care * * *". Functional assessments of therapy need guide HHAs in determining whether continued therapy is necessary. Therefore, we believe that the requirement to perform a functional assessment at the 13th and 19th visits, and at least every 30 days, will also not

create any burden on HHAs. Rather, we have clarified the minimum timeframes for functional assessments in the coverage regulations. Longstanding CoP policy at § 484.55 requires HHAs to document progress toward goals; therefore, we again do not believe that performing or documenting functional assessments at these 3 time-points would create a new burden. Both the functional assessment and its accompanying documentation are already part of existing HHA practices and accepted standards of clinical practice, and are approved under OMB# 0938–1083. Therefore, we do not believe these proposed requirements place any new documentation requirements on HHAs. We also believe that a prudent HHA would self-impose these requirements in the course of doing business.

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

B. ICRs Regarding HHA Capitalization

As stated above, we are revising § 489.28(a) to state that a newly enrolling HHA must consistently maintain sufficient capitalization between the time it submits its enrollment application until 3 months after its provider agreement becomes effective. The HHA will therefore be required to submit proof of capitalization at multiple points during this period.

In the proposed rule, we estimated that a newly enrolling HHA would be required to submit such proof 3 times prior to receiving Medicare billing privileges, and that the burden involved in doing so would be 1.5 hours on each occasion. We further projected that 500 newly enrolling HHAs (of which 200 would become enrolled) would be requested to furnish this data. The total annual burden would therefore be 2,250 hours (500 HHAs × 3 submissions × 1.5 hours).

We are adopting the aforementioned estimates for this final rule. These estimates are reflected in Table 14.

TABLE 14—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

OMB No.	Requirement	Respondents	Responses	Hour burden	Total
None	§ 489.28(a)	500	500	4.5	2,250

C. ICRs Regarding the Home Health Face-To-Face Encounter Requirement

The Affordable Care Act amends the requirements for physician certification of HH services contained in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act by requiring that prior to certifying a patient as eligible for HH services, the physician must document that the physician/NPP has had a face-to-face encounter (including through the use of telehealth. The Affordable Care Act provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's HH benefit (see sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act). In this rule, we are amending § 424.22(a)(1)(v) to require the certifying physician sign and date the documentation entry into the certification that the face-to-face patient encounter occurred no more than 90 days prior to the HH start of care date by himself or herself, or by an allowed NPP for initial certifications. We are requiring that the certifying physician's documentation of the face-to-face patient encounter be either a separate and distinct area on the certification, or a separate and distinct addendum to the certification, that is easily identifiable and clearly titled, dated, and signed by the certifying physician, and that it include the clinical findings of that encounter.

The burden associated with the documentation requirement for the patient's face-to-face encounter by the physician and certain allowed nonphysician practitioners includes the time for each HHA to develop a revised certification form or certification addendum which the HHA provides to the physician. The revised certification form or addendum to the certification must allow the physician to record that a face-to-face patient encounter has occurred. The revised form or addendum must also include the patient's name, a designated space for the physician to provide the date of the patient encounter, a designated space for the physician's documentation of the face-to-face encounter, and a designated space for the physician to provide his/her signature and the date signed.

There were 9,432 HHAs that filed claims in CY 2008. We estimate it would take each HHA 15 minutes of the HH administrator's time to develop and review the above described form language and 15 minutes of clerical time for each HHA to revise their existing initial certification form or to create an addendum with that form language. The estimated total one-time burden for developing the patient encounter form would be 4,716 hours.

The certifying physician's burden for composing the face-to-face documentation which includes how the clinical findings of the encounter support eligibility; writing, typing, or dictating the face-to-face documentation; signing, and dating the patient's face-to-face encounter is estimated at 5 minutes for each certification. We estimate that there would be 2,926,420 initial HH episodes in a year based on our 2008 claims data. As such, the estimated burden for documenting, signing, and dating the patient's face-to-face encounter would be 243,868 hours for CY 2011.

We reiterate that our longstanding policy has been that physicians must sign and date the certification statement that the patient is in need of HH services and meets the eligibility requirements to receive the benefit. Therefore, our making this requirement explicit in the regulation poses no additional burden to HHAs.

Additionally, it has been our longstanding manual policy that physicians must sign and date the certification and any recertifications. Our current regulations only address the physician's signing of the certification and recertification. In this rulemaking, we are strengthening our regulations at § 424.22 to achieve consistency with the timing and documentation of the face-to-face encounter and to mirror our longstanding manual policy by revising our regulations to make it a requirement that physicians not only sign, but also date certifications and recertifications. Because it has been our longstanding manual policy that physicians sign and date certifications and recertifications, and we are merely making this requirement explicit in our regulations, there is no additional burden to physicians.

Based on the criteria for payment of physician supervision of a patient receiving Medicare-covered services provided by a participating HHA as stipulated in the description of HCPC code G0181, our making the patient encounter requirement explicit in the regulation poses no additional burden to physician offices. Tables 15 and 16

summarize the burden estimate associated with these requirements.

TABLE 15—ESTIMATED ONE-TIME FORM DEVELOPMENT BURDEN

OMB No.	Requirement	HHAs	Responses	Hour burden	Total (hours)
0938–1083	§ 424.22(a)(1)(v)	9,432	1	.5	4,716

TABLE 16—ESTIMATED PHYSICIANS BURDEN FOR DOCUMENTING, SIGNING, AND DATING ENCOUNTER

OMB No.	Requirement	Patients	Responses	Hour burden	Total (hours)
0938–1083	§ 424.22(a)(1)(v)	2,926,420	1	.0833333	243,868

Details of our burden estimates are availabe in the Paperwork Reduction Act (PRA) package approved under OMB# 0938–1083. We are revising this currently approved package to incorporate these requirements.

D. ICRs Regarding the Requirements for Hospice Certification Changes

As described previously in this final rule, as of January 1, 2011 the Affordable Care Act requires physicians or NPs to attest that they determined continued hospice eligibility through a face-to-face encounter with all hospice patients prior to the 3rd benefit period recertification and at every subsequent recertification. We will require the physician or NP to sign and date an attestation statement that he or she had a face-to-face encounter with the patient, and include the date of that visit. This attestation would be a separate and distinct part of the physician recertification, or an addendum to the physician recertification.

The burden associated with this attestation requirement is the time for each hospice to develop simple attestation language to attach as an addendum or include as part of the recertification document, and the time for the physician or NP to include the patient name, the date that the patient was visited, the visiting physician or NP signature, and the date signed. As of February 2010, there were 3,429 hospices with claims filed in FY 2009. We estimate it would take each hospice 15 minutes of administrative time to develop and review the attestation language, and 15 minutes of clerical time to revise their existing recertification form or to create an addendum. The estimated total one-time burden for developing the attestation form would be 1,714 hours.

The burden for completing the attestation form is estimated at 30 seconds for each recertification at 180 days or beyond. We used the distribution of lengths of stay from hospice claims data to estimate the percentage of patients who required recertification at 180 days, and at subsequent 60-day benefit periods. We estimated that there would be 457,382 recertifications at 180 days or beyond, each of which requires an attestation. We assume that 90 percent of the visits were performed by physicians and 10 percent by nurse practitioners, based on our analysis of FY 2009 physician and NP hospice billing data, with 30 seconds time allowed to sign and date the attestation statement, and to write in the name of the patient and the date of the visit, resulting in an estimated total burden to complete the attestation form of 3,811 hours for CY 2011. In the FY 2010 hospice rule (74 FR 39384), we finalized a requirement that the recertifying physician include a brief narrative explanation of the clinical findings which support continued hospice eligibility. Effective January 1, 2011, regulation text changes to require this narrative to describe why the clinical findings of the face-to-face encounter, occurring at the 180-day recertification and all subsequent recertifications, continue to support hospice eligibility. However, these regulation changes are for clarification. The narrative requirement finalized in FY 2010 requires that the narrative include why the clinical findings of any physician/NP/patient encounter support continued hospice eligibility. Therefore, the only documentation burden associated with this requirement is the signed and dated attestation that the encounter occurred.

In addition, commenters asked that we change the regulatory language at § 418.22(b)(3)(iii) to require the physician's signature to follow the narrative attestation statement, rather than to be above it on the form. The commenters believed that the signature should "close the loop", and that this placement would be consistent with the face-to-face attestation requirements. We agree with the commenters, and are finalizing this as a change in the regulation. We do not believe that moving the signature underneath the narrative attestation (rather than leaving it above it) creates any additional burden to hospices. The estimate of administrative burden to create the face-to-face attestation includes enough administrative time for form revision to cover moving the narrative attestation signature line.

We reiterate that our longstanding policy has been that physicians must sign and date the certification and any recertifications. Therefore, our making this requirement explicit in the regulation poses no additional burden to hospices. We also clarified the timeframe which the certifications and recertifications cover by requiring physicians to include the dates of the benefit period to which the certification or recertification applies. We believe this is already standard practice at nearly all hospices, but are addressing it in regulation. Using the distribution of lengths of stay from 2007 and 2008 claims data, we estimate that there would be 1,733,663 initial certifications and recertifications during the course of a year. We estimate that it would take a physician 30 seconds at most to include the benefit period dates. We estimate that the time to require physicians to include the benefit period dates on the certification or recertification would be 30 seconds per certification or recertification, for a total burden of 14,447 hours for CY 2011. Table 17 summarizes the burden estimate associated with these requirements.

TABLE 17—ESTIMATED ANNUAL RECORDKEEPING BURDEN

OMB No.	Requirements	Units	Responses	Hour burden	Total
0938–1067	418.22(b)(4)	3,429 hospices	1	0.50	1,714
0938–1067	418.22(b)(4)	457,382 ≥180-day recerts	1	0.0083333	3,811
0938–1067	418.22(b)(5)	1,733,663 All certs. & recerts	1	0.0083333	14,447

Details of our burden estimates are available in the PRA package approved under OMB# 0938–1067. We are revising this currently approved package to incorporate these requirements.

We received one comment about the burden estimate of the hospice face-to-face attestation, and one about an addition to the face-to-face attestation.

Comment: A commenter wrote that the administrative burden calculated by CMS did not include the staff time required to track down these face-to-face encounters. The administrative cost that was calculated is not included in the reimbursement for hospices.

Response: The above mentioned burden estimate only reflects the burden associated with any additional required *documentation.* In this case, the additional required documentation is the attestation of the face-to-face encounter. Our burden estimate includes the administrative time to develop an attestation form as well as the time that we believe would be required to revise the hospice's existing certification or recertification forms, if necessary. The requirement as stated in § 418.22 pertains to additional documentation only, that is, documentation requirements subsequent to the face-to-face encounter; therefore, the estimate above does not include any burden associated with the administrative coordination and conduct of face-to-face encounters or tracking the encounters.

E. ICRs Regarding the Home Health Care CAHPS Survey (HHCAHPS)

As part of the DHHS Transparency Initiative on Quality Reporting, we are implementing a process to measure and publicly report patients' experiences with HH care they receive from Medicare-certified HHAs with the Home Health Care CAHPS (HHCAHPS) survey. The HHCAHPS was developed and tested by the Agency for Healthcare Research and Quality (AHRQ) and is part of the family of CAHPS surveys, is a standardized survey for HH patients to assess their HH care providers and the quality of the HH care they received. Prior to the HHCAHPS, there was no national standard for collecting data about HH care patients' perspectives of their HH care.

Section 484.250, Patient Assessment Data, will require an HHA to submit to CMS HHCAHPS data in order for CMS to administer the payment rate methodologies described in § 484.215, § 484.230, and § 484.235. The burden associated with this is the time and effort put forth by the HHA to submit the HHCAHPS data, the patient burden to respond to the survey, and the cost to the HHA to pay the survey vendor to collect the data on their behalf. This burden is currently accounted for under OMB# 0938–1066.

The HHCAHPS survey received OMB clearance on July 18, 2009, and the number is 0938–1066. In that PRA package, we did not state the burden to the HHAs concerning the hours that they would need to secure an approved HHCAHPS vendor and to pay for that vendor. In this rule, we have included the burden directly affecting HHAs, which is the burden to select a survey vendor from *http://www.homehealthcahps.org* and to sign a contract with that survey vendor that will conduct HHCAHPS on behalf of the HHA. We have determined that this would take 16.0 hours for each HHA. It is noted that 91 percent of all HHAs (9,890 HHAs of a total of 10,998 HHAs) would be conducting HHCAHPS, since about 9 percent of HHAs will be exempt from conducting HHCAHPS because they have less than 60 eligible patients in the year. In Table 18, we have listed this burden to the HHAs:

TABLE 18—ESTIMATED ANNUAL BURDEN ON HHAS FOR VENDOR SELECTION

OMB No.	Requirements	Units	Responses	Hour burden	Total
0938–1066	§ 484.250(c)(2)	9,890	1	16.0	158,240

OMB Number 0938–1066 will be revised to reflect the update concerning burden to the HHAs for vendor services for HHCAHPS.

Section 5201 of the DRA requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to payment. This requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH market basket percentage increase will be reduced 2 percentage points. In accordance with the statue, we published a final rule (71 FR 65884, 65935) in the **Federal Register** on November 9, 2006 to implement the pay-for-reporting requirement of the DRA, codified at § 484.225(h) and (i).

In the CY 2010 HH PPS proposed rule (August 13, 2009), we to expand the HH quality measures reporting requirements to include the CAHPS® Home Health Care (HHCAHPS) Survey, as initially discussed in the May 4, 2007 proposed rule (72 FR 25356, 25452) and in the November 3, 2008 Notice (73 FR 65357,65358). As part of the DHHS Transparency Initiative, we proposed to implement a process to measure and publicly report patient experiences with HH care using a survey developed by AHRQ in its CAHPS® program. In the CY 2010 HH PPS final rule, we stated our intention to move forward with the HHCAHPS and link the survey to the CY 2012 annual payment update under the DRA "pay-for-reporting" requirement.

As part of this requirement, each HHA sponsoring a HHCAHPS Survey must prepare and submit to its survey vendor a file containing patient data on patients served the preceding month that will be used by the survey vendor to select the sample and field the survey. This file (essentially the sampling frame) for most HHAs can be generated from existing databases with minimal effort. For some small HHAs, preparation of a monthly sample frame may require more time. However, data elements needed on the sample frame will be kept at a minimum to reduce the burden on all HHAs.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget.

Attention: CMS Desk Officer, [CMS–1510–F]

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

1. CY 2011 Update

The update set forth in this final rule applies to Medicare payments under HH PPS in CY 2011. Accordingly, the following analysis describes the impact in CY 2011 only. We estimate that the net impact of the proposals in this rule is approximately $960 million in CY 2011 savings. The $960 million impact to the proposed CY 2011 HH PPS reflects the distributional effects of an updated wage index ($20 million increase) plus the 1.1 percent HH market basket update ($210 million increase), for a total increase of $230 million. The 3.79 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($700 million decrease) plus the 2.5 percent returned from the outlier provisions of the Affordable Care Act ($490 million decrease) results in a total decrease of $1,190 million, which, when added to the $230 million increase, totals savings of $960 million in CY 2011. The $960 million in savings is reflected in the first row of column 3 of Table 19 below as a 4.89 percent decrease in expenditures when comparing the current CY 2010 HH PPS to the proposed CY 2011 HH PPS.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to $34.5 million in any 1 year. For the purposes of the RFA, our updated data show that approximately 95 percent of HHAs are considered to be small businesses according to the Small Business Administration's size standards with total revenues of $13.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this final rule would have a significant economic impact on a substantial number of small entities. In the proposed rule, we stated that our analysis reveals that nominal case-mix continues to grow under the HH PPS. Specifically, nominal case-mix has grown from the 11.75 percent growth identified in our analysis for CY 2008 rulemaking to 17.45 percent for this year's rulemaking. Because we have not yet accounted for all of the increase in nominal case-mix, that is case-mix that is not real (real being related to treatment of more resource intense patients), case-mix reductions are necessary. As such, we believe it appropriate to reduce the HH PPS rates now, so as to move towards more accurate payment for the delivery of HH services. We have amended the proposal that would have implemented two successive years of payment reductions, with each year's reduction at 3.79 percent. Instead we are finalizing in this rule only the first year's reduction (for CY 2011) while we study additional case-mix data, and methods to incorporate such data, into our methodology for measuring real vs. nominal case-mix change. Other reductions to HH PPS payments discussed in this rule were mandated in provisions in the Affordable Care Act. Our analysis shows that small HHAs and large HHAs are impacted relatively similarly by the final provisions of this rule. Further detailed impact assessment, by facility type, is presented in the analysis below.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule applies to HHAs. Therefore, the Secretary has determined that this final rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. This final rule is not anticipated to have an effect on State, local, or tribal governments in the aggregate, or on the private sector, of $135 million or more.

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

B. Anticipated Effects

This final rule sets forth updates to the HH PPS rates contained in the CY 2010 notice published on November 10, 2009. The impact analysis of this final rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such

variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based on Medicare claims from 2008. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the BBA, the BBRA, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the MMA, the DRA, the Affordable Care Act, or new statutory provision. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 19 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule. For this analysis, we used linked HH claims and OASIS assessments; the claims represented a 20-percent sample of 60-day episodes occurring in CY 2008. The first column of Table 19 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the payment effects of the wage index only. The third column shows the payment effects of all the policies outlined earlier in this rule. For CY 2011, the average impact for all HHAs is a .08 percent increase in payments due to the effects of the wage index. The overall impact, for all HHAs, in estimated total payments from CY 2010 to CY 2011, is a decrease of approximately 4.89 percent. There is very little difference in the estimated impact on HHAs when looking at the type of facility. Freestanding HHAs are estimated to see a 4.88 percent decrease in payments while facility based HHAs are estimated to see a 4.92 percent decrease. Similarly, voluntary not-for-profit HHAs are estimated to see a 4.97 percent decrease in payments, while for-profit HHAs are estimated to see a 4.84 percent decrease in payments. Rural agencies are estimated to see a 4.67 percent decrease in payment in CY 2011, while urban agencies are estimated to see a 4.93 percent decrease in payments. Agencies in New England (−5.39 percent) and in the South (−5.19 percent) are estimated to experience the largest decreases, while HHAs in the Pacific (−4.49 percent) and the West (−4.66 percent) are estimated to have less of a decrease in payments in CY 2011. In general, smaller agencies are estimated to see less of a decrease in payments in CY 2011, than are larger agencies, with agencies with 100–199 first episodes estimated to see a 4.73 percent decrease and agencies with 200 or more first episodes estimated to see a 4.93 percent decrease in payment in CY 2011.

We supplemented our impact analysis from the proposed rule by linking to Medicare cost report data which has total revenues for HHAs. Using total revenues and the $13.5 million threshold of the RFA, we categorized an HHA as being either small or large. To perform this analysis, we were able to match approximately 72 percent of the cost report data to our model. For the remainder of the agencies in the model, we proxy for large agencies as those agencies with at least 750 first episodes (doing so results in approximately 95 percent of agencies being classified as small and 5 percent of agencies being large, which is reflective of what our cost report files show us). This analysis provides similar results to the one using first episodes as a measure of an agency's size in that small HHAs fare slightly better, a 4.84 percent decrease in payments, than do large HHAs, which are estimated to experience a 5.01 percent decrease in payments in CY 2011.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA. The amended section 421(a) of the MMA provides an increase of 3 percent of the payment amount otherwise made for HH services furnished in a rural area, with respect to episodes and visits ending on or after April 1, 2010 and before January 1, 2016. Column 3 of Table 19 displays a comparison of estimated payments in CY 2010, including a 3 percent rural add-on for the last three quarters of CY 2010, to estimated payments in CY 2011, including a 3 percent rural add-on for all four quarters of CY 2011.

TABLE 19—IMPACTS BY AGENCY TYPE

Group	Comparisons	
	Percent change due to the effects of the updated wage index only	Impact of all CY 2011 policies [1] (percent)
All Agencies:	0.08	−4.89
Type of Facility:		
Free-Standing/Other Vol/NP	−0.10	−4.99
Free-Standing/Other Proprietary	0.16	−4.85
Free-Standing/Other Government	−0.23	−4.97
Facility-Based Vol/NP	−0.08	−4.95
Facility-Based Proprietary	0.20	−4.68
Facility-Based Government	−0.06	−4.86
Subtotal: Freestanding	0.10	−4.88
Subtotal: Facility-based	−0.05	−4.92
Subtotal: Vol/NP	−0.09	−4.97
Subtotal: Proprietary	0.17	−4.84
Subtotal: Government	−0.15	−4.92
Type of Facility (Rural * Only):		
Free-Standing/Other Vol/NP	0.00	−4.70
Free-Standing/Other Proprietary	0.26	−4.61
Free-Standing/Other Government	−0.43	−5.01
Facility-Based Vol/NP	−0.10	−4.73
Facility-Based Proprietary	0.20	−4.53

TABLE 19—IMPACTS BY AGENCY TYPE—Continued

Group	Comparisons	
	Percent change due to the effects of the updated wage index only	Impact of all CY 2011 policies [1] (percent)
Facility-Based Government	−0.12	−4.78
Type of Facility (Urban * Only):		
Free-Standing/Other Vol/NP	−0.12	−5.03
Free-Standing/Other Proprietary	0.15	−4.89
Free-Standing/Other Government	0.02	−4.93
Facility-Based Vol/NP	−0.07	−5.01
Facility-Based Proprietary	0.20	−4.78
Facility-Based Government	0.03	−4.95
Type of Facility (Urban* or Rural*):		
Rural	0.10	−4.67
Urban	0.07	−4.93
Facility Location: Region*:		
North	−0.34	−5.19
South	0.18	−4.80
Midwest	0.01	−4.98
West	0.33	−4.66
Outlying	−0.11	−5.03
Facility Location:		
Area of the Country:		
New England	−0.54	−5.39
Mid Atlantic	−0.23	−5.08
South Atlantic	0.05	−4.94
East South Central	−0.09	−5.04
West South Central	0.41	−4.58
East North Central	0.07	−4.95
West North Central	−0.22	−5.11
Mountain	−0.15	−5.05
Pacific	0.54	−4.49
Outlying	−0.11	−5.03
Facility Size: (Number of First Episodes):		
< 19	0.21	−4.88
20 to 49	0.20	−4.86
50 to 99	0.26	−4.77
100 to 199	0.25	−4.73
200 or More	0.01	−4.93
Facility Size: (estimated total revenue)		
Small (estimated total revenue <= $13.5 million)	0.14	−4.84
Large (estimated total revenue > $13.5 million)	−0.08	−5.01

Note: Based on a 20 percent sample of CY 2008 claims linked to OASIS assessments.

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

REGION KEY:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic** = Pennsylvania, New Jersey, New York; **South Atlantic** = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central** = Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central** = Alabama, Kentucky, Mississippi, Tennessee; **West North Central** = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central** = Arkansas, Louisiana, Oklahoma, Texas; **Mountain** = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific** = Alaska, California, Hawaii, Oregon, Washington; **Outlying** = Guam, Puerto Rico, Virgin Islands.

[1] Percent change due to the effects of the update wage index, the 1.1 percent HH market basket update, the 3.79 percent reduction to the national standardized episode rates, the national per-visit rates, the LUPA add-on payment amount, the 5 percent decrease in the rates due to the Affordable Care Act, the new approximate 2.5 percent target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, 10 percent outlier cap, and the 3 percent rural add-on.

In a separate, supplemental analysis, as merely an indicator of possible access to care issues, we looked at estimated margins of HHAs, by county, and the estimated effect that the provisions of this rule might have on HHA margins. We note that predicting the size of the increase in negative-margin agencies as a result of this rule is difficult to do because many agencies may find ways to cut costs or increase revenues so that margins do not deteriorate. We also note that margin analysis alone is not an accurate access to care indicator. Many factors affect whether agencies with low or negative margin would close or not, such as the organization's mission, the availability of alternate sources of funding, and whether or not the organization is embedded in a larger one.

We performed the following analysis for the purposes of identifying potential access risks associated with this rule. In particular, we looked to identify whether the finalized policies of this rule might increase the number of counties not served by at least one HHA with a positive margin. The analysis demonstrated that the occurrence of such counties was very infrequent. Looking further, we also identified that the counties we identified had at least one HHA in a contiguous county with a positive margin. As we have previously described, we believe HH

industry margins are sufficient to support a rate reduction of this size. We note here as we have elsewhere in this rule that MedPac projected 2011 margins would remain high, at 13.7 percent (assuming the previously planned rate reduction of −2.71 percent in 2011), and MedPAC also reported that the number of agencies continues to grow, reaching in excess of 10,400 in 2009, a 50 percent increase since 2002. We again note that access to care was not found to be inadequate in 2002, when the number of agencies nationally was much lower than it is today. Thus, we do not believe that the finalized policies in this rule will result in access to care issues. We would note that the above described analysis is an indicator that access to care will not be an issue as a result of the provisions of this rule.

C. Alternative Considered

As stated above, in section IV.A. of this rule, Overall Impact, we estimate that this final rule would have a significant economic impact on a substantial number of small entities. In the proposed rule, our analysis on the impact on small HHAs was from an episodic perspective. As a result of the public comments received on the proposed rule, we supplemented our impact from the proposed rule by linking to Medicare cost report data, which has reported total revenues for HHAs. The results of that supplemental analysis reveal that in using Medicare cost report data and a $13.5 million threshold to determine small versus large HHAs, the effect on small HHAs is virtually unchanged from that which was described in the proposed rule.

In CY 2008 rulemaking, we promulgated case-mix reductions of 2.75 percent for CY 2008, CY 2009, CY 2010, and 2.71 percent for CY 2011. Since that rulemaking, our analysis still shows that case-mix continues to grow. More specifically, nominal case-mix has grown from the 11.75 percent growth identified in our analysis for the CY 2008 rulemaking to 17.45 percent for this rule. While the 2.71 percent case-mix reduction was promulgated in CY 2008 rulemaking, because nominal case-mix continues to grow and thus to date we have not accounted for all of the increase in nominal case-mix growth, we believe it appropriate to reduce HH PPS rates now, so as to move towards more accurate payment for the delivery of HH services under the Medicare HH benefit.

Furthermore, we have amended our proposal from the proposed rule, which would have implemented 2 successive years of case-mix reductions at 3.79 percent, and are instead finalizing only one 3.79 percent reduction for CY 2011. We will study additional case-mix data, and methods to incorporate such data, into our methodology for measuring real versus nominal case-mix change in future rulemaking.

The other reductions to the HH PPS payments discussed in this rule and included in the final provisions of this rule are not discretionary as they are required by the Affordable Care Act.

D. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the classification of the expenditures associated with the provisions of this final rule.

Table 20 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this final rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $960 million.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2010 HH PPS CALENDAR YEAR TO THE 2011 HH PPS CALENDAR YEAR

Category	Transfers
Annualized Monetized Transfers.	Negative transfer—Estimated decrease in expenditures: $960 million.
From Whom to Whom	Federal Government to HH providers.

E. Conclusion

In conclusion, we estimate that the net impact of the proposals in this rule is approximately $960 million in CY 2011 savings. The $960 million impact to the proposed CY 2011 HH PPS reflects the distributional effects of an updated wage index ($20 million increase), the 1.1 percent HH market basket update ($210 million increase), the 3.79 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($700 million decrease), as well as the 2.5 percent returned from the outlier provisions of the Affordable Care Act ($490 million decrease). This analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health Professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapters IV and V as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

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

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

Subpart E—Home Health Services Under Hospital Insurance

■ 2. Section 409.44 is amended by revising paragraphs (c)(1), (c)(2)(i), (c)(2)(iii), and (c)(2)(iv) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

(c) * * *

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes. To be covered by Medicare, all of the requirements apply as follows:

(i) The patient's plan of care must describe a course of therapy treatment and therapy goals which are consistent with the evaluation of the patient's

function, and both must be included in the clinical record. The therapy goals must be established by a qualified therapist in conjunction with the physician.

(ii) The patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice.

(iii) Therapy treatment goals described in the plan of care must be measurable, and must pertain directly to the patient's illness or injury, and the patient's resultant impairments.

(iv) The patient's clinical record must demonstrate that the method used to assess a patient's function included objective measurements of function in accordance with accepted professional standards of clinical practice enabling comparison of successive measurements to determine the effectiveness of therapy goals. Such objective measurements would be made by the qualified therapist using measurements which assess activities of daily living that may include but are not limited to eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, or using assistive devices, and mental and cognitive factors.

(2) * * *

(i) The services must be considered under accepted standards of professional clinical practice, to be a specific, safe, and effective treatment for the beneficiary's condition. Each of the following requirements must also be met:

(A) The patient's function must be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method which would include objective measurement as described in § 409.44(c)(1)(iv). If more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must perform the assessment and periodic reassessments. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record.

(B) At least every 30 days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least every 30 days.

(C) If a patient is expected to require 13 therapy visits, a qualified therapist (instead of an assistant) must provide all of the therapy services on the 13th therapy visit and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). Exceptions to this requirement are as follows:

(*1*) The qualified therapist's visit can occur after the 10th therapy visit but no later than the 13th therapy visit when the patient resides in a rural area or when documented circumstances outside the control of the therapist prevent the qualified therapist's visit at the 13th therapy visit.

(*2*) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide all of the therapy services and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) during the visit associated with that discipline which is scheduled to occur close to but no later than the 13th therapy visit per the plan of care.

(D) If a patient is expected to require 19 therapy visits, a qualified therapist (instead of an assistant) must provide all of the therapy services on the 19th therapy visit and functionally reassess the patient in accordance with § 409.44(c)(2)(A). Exceptions to this requirement are as follows:

(*1*) This required qualified therapist service can instead occur after the 16th therapy visit but no later than the 19th therapy visit when the patient resides in a rural area or documented circumstances outside the control of the therapist preclude the qualified therapist service at the 19th therapy visit.

(*2*) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide the therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) during the visit which would occur close to but before the 19th visit per the plan of care.

(E) Pursuant to the requirements described in paragraphs (c)(2)(i)(A)(B), (C), and (D) above, subsequent therapy visits will not be covered until the following conditions are met:

(*1*) The qualified therapist has completed the reassessment and objective measurement of the effectiveness of the therapy as it relates to the therapy goals.

(*2*) The qualified therapist has determined if goals have been achieved or require updating.

(*3*) The qualified therapist has documented measurement results and corresponding therapy effectiveness in the clinical record in accordance with § 409.44(c)(2)(i)(H) of this section.

(F) If the criteria for maintenance therapy, described at § 409.44(c)(2)(iii)(B) and (C) of this section are not met, the following criteria must also be met for subsequent therapy visits to be covered:

(*1*) If the objective measurements of the reassessment do not reveal progress toward goals, the qualified therapist together with the physician must determine whether the therapy is still effective or should be discontinued.

(*2*) If therapy is to be continued in accordance with § 409.44(c)(2)(iv)(B)(*1*) of this section, the clinical record must document with a clinically supportable statement why there is an expectation that the goals are attainable in a reasonable and generally predictable period of time.

(G) Clinical notes written by therapy assistants may supplement the clinical record, and if included, must include the date written, the signature, professional designation, and objective measurements or description of changes in status (if any) relative to each goal being addressed by treatment. Assistants may not make clinical judgments about why progress was or was not made, but must report the progress or the effectiveness of the therapy (or lack thereof) objectively.

(H) Documentation by a qualified therapist must include the following:

(*1*) The therapist's assessment of the effectiveness of the therapy as it relates to the therapy goals;

(*2*) Plans for continuing or discontinuing treatment with reference to evaluation results and or treatment plan revisions;

(*3*) Changes to therapy goals or an updated plan of care that is sent to the physician for signature or discharge;

(*4*) Documentation of objective evidence or a clinically supportable statement of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy in a reasonable and generally predictable period of time; or in the case of maintenance therapy, the patient is responding to therapy and can meet the goals in a predictable period of time.

* * * * *

(iii) For therapy services to be covered in the home health setting, one of the following three criteria must be met:

(A) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition.

(*1*) Material improvement requires that the clinical record demonstrate that the patient is making improvement towards goals when measured against his or her condition at the start of treatment.

(*2*) If an individual's expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to achieve such potential, therapy would not be considered reasonable and necessary, and thus would not be covered.

(*3*) When a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, because the services do not require the performance or supervision of a qualified therapist, those services are not to be considered reasonable and necessary covered therapy services.

(B) The unique clinical condition of a patient may require the specialized skills, knowledge, and judgment of a qualified therapist to design or establish a safe and effective maintenance program required in connection with the patient's specific illness or injury.

(*1*) If the services are for the establishment of a maintenance program, they must include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary periodic reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(*2*) The maintenance program must be established by a qualified therapist (and not an assistant).

(C) The unique clinical condition of a patient may require the specialized skills of a qualified therapist to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the complexity of the therapy services required to maintain function involve the use of complex and sophisticated therapy procedures to be delivered by the therapist himself/herself (and not an assistant) or the clinical condition of the patient is such that the complexity of the therapy services required to maintain function must be delivered by the therapist himself/herself (and not an assistant) in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services shall be covered.

(iv) The amount, frequency, and duration of the services must be reasonable and necessary, as determined by a qualified therapist and/or physician, using accepted standards of clinical practice.

(A) Where factors exist that would influence the amount, frequency or duration of therapy services, such as factors that may result in providing more services than are typical for the patient's condition, those factors must be documented in the plan of care and/or functional assessment.

(B) Clinical records must include documentation using objective measures that the patient continues to progress towards goals. If progress cannot be measured, and continued progress towards goals cannot be expected, therapy services cease to be covered except when—

(*1*) Therapy progress regresses or plateaus, and the reasons for lack of progress are documented to include justification that continued therapy treatment will lead to resumption of progress toward goals; or

(*2*) Maintenance therapy as described in § 409.44(c)(2)(iii)(B) or (C) is needed.

PART 418—HOSPICE CARE

■ 3. The authority citation for part 418 continues to read as follows:

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

Subpart B—Eligibility, Election and Duration of Benefits

■ 4. Section 418.22 is amended by—
■ A. Revising paragraphs (a)(3) and (b)(3)(iii).
■ B. Adding paragraphs (a)(4), (b)(3)(v), (b)(4), and (b)(5).

The revisions and additions read as follows:

§ 418.22 Certification of terminal illness.

(a) * * *

(3) *Exceptions.* (i) If the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(ii) Certifications may be completed no more than 15 calendar days prior to the effective date of election.

(iii) Recertifications may be completed no more than 15 calendar days prior to the start of the subsequent benefit period.

(4) *Face-to-face encounter.* As of January 1, 2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice patient, whose total stay across all hospices is anticipated to reach the 3rd benefit period, no more than 30 calendar days prior to the 3rd benefit period recertification, and must have a face-to-face encounter with that patient no more than 30 calendar days prior to every recertification thereafter, to gather clinical findings to determine continued eligibility for hospice care.

(b) * * *

(3) * * *

(iii) The narrative shall include a statement directly above the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient.

* * * * *

(v) The narrative associated with the 3rd benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less.

(4) The physician or nurse practitioner who performs the face-to-face encounter with the patient described in (a)(4), must attest in writing that he or she had a face-to-face encounter with the patient, including the date of that visit. The attestation of the nurse practitioner shall state that the clinical findings of that visit were provided to the certifying physician, for use in determining whether the patient continues to have a life expectancy of 6 months or less, should the illness run its normal course. The attestation, its accompanying signature, and the date signed, must be a separate and distinct section of, or an addendum to, the recertification form, and must be clearly titled.

(5) All certifications and recertifications must be signed and dated by the physician(s), and must include the benefit period dates to which the certification or recertification applies.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 5. The authority citation for part 424 continues to read as follows:

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

Subpart B—Certification and Plan Requirements

■ 6. Section 424.22 is amended by—
■ A. Adding paragraph (a)(1)(v).

■ B. Revising paragraph (a)(2), (b)(1), and (d).

The revisions and additions read as follows:

§ 424.22 Requirements for home health services.

(a) * * *

(1) * * *

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) respectively. Under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, the face-to-face encounter must be performed by the certifying physician himself or herself or by a nurse practitioner, a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, a certified nurse midwife (as defined in section 1861(gg)of the Act) as authorized by State law, or a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician. The documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled, dated and signed by the certifying physician.

(A) The nonphysician practitioner performing the face-to-face encounter must document the clinical findings of that face-to-face patient encounter and communicate those findings to the certifying physician.

(B) If a face-to-face patient encounter occurred within 90 days of the start of care but is not related to the primary reason the patient requires home health services, or the patient has not seen the certifying physician or allowed nonphysician practitioner within the 90 days prior to the start of the home health episode, the certifying physician or nonphysician practitioner must have a face to face encounter with the patient within 30 days of the start of the home health care.

(C) The face-to-face patient encounter may occur through telehealth, in compliance with Section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

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

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(b) * * *

(1) *Timing and signature of recertification.* Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

* * * * *

(d) *Limitation of the performance of physician certification and plan of care functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician who has a financial relationship as defined in § 411.354 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(1) If a physician has a financial relationship as defined in § 411.354 of this chapter, with an HHA, the physician may not certify or recertify need for home health services provided by that HHA, establish or review a plan of treatment for such services, or conduct the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act unless the financial relationship meets one of the exceptions set forth in § 411.355 through § 411.357 of this chapter.

(2) A Nonphysician practitioner may not perform the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act if such encounter would be prohibited under paragraph (d)(i) if the nonphysician practitioner were a physician.

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

■ 7. Section 424.502 is amended by adding the definition of "Change in Majority Ownership" in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Change in Majority Ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

* * * * *

■ 8. Section 424.510 is amended by adding paragraph (d)(9) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(9) In order to obtain enrollment and to maintain enrollment for the first three months after Medicare billing privileges are conveyed, a home health agency must satisfy the home health "initial reserve operating funds" requirement as set forth in § 489.28 of this chapter.

* * * * *

■ 9. Section 424.530 is amended by adding paragraph (a)(8)to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(8) *Initial Reserve Operating Funds.* (i) CMS or its designated Medicare

contractor may deny Medicare billing privileges if, within 30 days of a CMS or Medicare contractor request, a home health agency (HHA) cannot furnish supporting documentation which verifies that the HHA meets the initial reserve operating funds requirement found in § 489.28(a) of this title.

(ii) CMS may deny Medicare billing privileges upon an HHA applicant's failure to satisfy the initial reserve operating funds requirement found in 42 CFR 489.28(a).

* * * * *

■ 10. Section 424.535 is amended by adding paragraph (a)(11) to read as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) * * *

(11) Initial Reserve Operating Funds. CMS or its designated Medicare contractor may revoke the Medicare billing privileges of an HHA and the corresponding provider agreement if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR § 489.28(a).

* * * * *

■ 11. Section 424.550 is amended by adding paragraphs (b)(1) and (b)(2) to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(1) Unless an exception in (b)(2) of this section applies, if there is a change in majority ownership of a home health agency by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

(i) Enroll in the Medicare program as a new (initial) HHA under the provisions of § 424.510 of this subpart.

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2)(i) The HHA submitted two consecutive years of full cost reports. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.

(ii) An HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(iii) The owners of an existing HHA are changing the HHA's existing business structure (for example, from a corporation to a partnership (general or limited); from an LLC to a corporation; from a partnership (general or limited) to an LLC) and the owners remain the same.

(iv) An individual owner of an HHA dies.

* * * * *

PART 484—HOME HEALTH SERVICES

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

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

Subpart E—Prospective Payment System for Home Health Agencies

■ 13. Section 484.250 is revised to read as follows:

§ 484.250 Patient assessment data.

(a) An HHA must submit to CMS the OASIS–C data described at § 484.55 (b)(1) and Home Health Care CAHPS data in order for CMS to administer the payment rate methodologies described in § 484.215, § 484.230, and § 484.235 of this subpart, and meet the quality reporting requirements of section 1895 (b)(3)(B)(v) of the Act.

(b) An HHA that has less than 60 eligible unique HHCAHPS patients annually must submit to CMS their total HHCAHPS patient count to CMS in order to be exempt from the HHCAHPS reporting requirements.

(c) An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf.

(1) CMS approves an HHCAHPS survey vendor if such applicant has been in business for a minimum of three years and has conducted surveys of individuals and samples for at least 2 years. For HHCAHPS, a "survey of individuals" is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes. All applicants that meet these requirements will be approved by CMS.

(2) No organization, firm, or business that owns, operates, or provides staffing for a HHA is permitted to administer its own Home Health Care CAHPS (HHCAHPS) Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations will not be approved by CMS as HHCAHPS survey vendors.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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

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

Subpart B—Essentials of Provider Agreements

■ 15. Section 489.28 is amended by—

■ A. Revising paragraphs (a) and (g).

■ B. Adding paragraph (c)(1).

■ C. Reserving paragraph (c)(2).

The addition and revisions read as follows:

§ 489.28 Special capitalization requirements for HHAs.

(a) *Basic rule.* An HHA entering the Medicare program on or after January 1, 1998, including a new HHA as a result of a change of ownership, if the change of ownership results in a new provider number being issued, must have available sufficient funds, which we term "initial reserve operating funds," at the time of application submission and at all times during the enrollment process up to the expiration of the 3-month period following the conveyance of Medicare billing privileges to operate the HHA for the three-month period after Medicare billing privileges are conveyed by the Medicare contractor, exclusive of actual or projected accounts receivable from Medicare.

* * * * *

(c) * * *

(1) In selecting the comparative HHAs as described in this paragraph (c), the CMS contractor shall only select HHAs that have provided cost reports to Medicare. When selecting cost reports for the comparative analysis, CMS will exclude low utilization or no utilization cost reports.

(2) [Reserved.]

* * * * *

(g) *Billing Privileges.* (1) CMS may deny Medicare billing privileges to an HHA unless the HHA meets the initial reserve operating funds requirements of this section.

(2) CMS may revoke the Medicare billing privileges of an HHA that fails to maintain and comply with the initial reserve operating funds requirements of this section for the three-month period after it receives its Medicare billing privileges.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—

Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 26, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 29, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Note: The following addenda will not be published in the Code of Federal Regulations.

BILLING CODE 4120–01–P

ADDENDUM A: CY 2011 WAGE INDEX BASED ON CBSA LABOR MARKET AREAS FOR RURAL AREAS;

CBSA Code	Nonurban Area	Wage Index
01	Alabama	0.7380
02	Alaska	1.2626
03	Arizona	0.9095
04	Arkansas	0.7222
05	California	1.2056
06	Colorado	0.9933
07	Connecticut	1.1128
08	Delaware	0.9757
10	Florida	0.8409
11	Georgia	0.7566
12	Hawaii	1.1189
13	Idaho	0.7556
14	Illinois	0.8343
15	Indiana	0.8391
16	Iowa	0.8545
17	Kansas	0.7981
18	Kentucky	0.7830
19	Louisiana	0.7712
20	Maine	0.8588
21	Maryland	0.9175
22	Massachusetts[1]	1.1769
23	Michigan	0.8555
24	Minnesota	0.9038
25	Mississippi	0.7620
26	Missouri	0.7655
27	Montana	0.8517
28	Nebraska	0.8911
29	Nevada	0.9350
30	New Hampshire	1.0207
31	New Jersey[1]	------
32	New Mexico	0.8911
33	New York	0.8185
34	North Carolina	0.8359
35	North Dakota	0.6831
36	Ohio	0.8561
37	Oklahoma	0.7860
38	Oregon	1.0029
39	Pennsylvania	0.8480
40	Puerto Rico[1]	0.4047
41	Rhode Island[1]	------
42	South Carolina	0.8413
43	South Dakota	0.8536
44	Tennessee	0.7886
45	Texas	0.7806
46	Utah	0.8649
47	Vermont	0.9591
48	Virgin Islands	0.7993
49	Virginia	0.7841
50	Washington	1.0184
51	West Virginia	0.7474
52	Wisconsin	0.9186
53	Wyoming	0.9528
65	Guam	0.9611

[1] All counties within the State are classified as urban, with the exception of Massachusetts and Puerto Rico. Massachusetts and Puerto Rico have areas designated as rural, however, no short-term, acute care hospitals are located in the area(s) for CY 2011

ADDENDUM B.- CY 2011 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10180	Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX	0.8003
10380	Aguadilla-Isabela-San Sebastián, PR Aguada Municipio, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR	0.3471
10420	Akron, OH Portage County, OH Summit County, OH	0.8843
10500	Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA	0.9036
10580	Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY	0.8653
10740	Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM	0.9456
10780	Alexandria, LA Grant Parish, LA Rapides Parish, LA	0.7995
10900	Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA	0.9194
11020	Altoona, PA Blair County, PA	0.8620
11100	Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX	0.8644
11180	Ames, IA Story County, IA	0.9970
11260	Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK	1.1964
11300	Anderson, IN Madison County, IN	0.9192
11340	Anderson, SC Anderson County, SC	0.8691
11460	Ann Arbor, MI Washtenaw County, MI	1.0124
11500	Anniston-Oxford, AL Calhoun County, AL	0.7918
11540	Appleton, WI Calumet County, WI Outagamie County, WI	0.9361
11700	Asheville, NC Buncombe County, NC Haywood County, NC Henderson County, NC Madison County, NC	0.9001
12020	Athens-Clarke County, GA Clarke County, GA Madison County, GA Oconee County, GA Oglethorpe County, GA	0.9659

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12060	Atlanta-Sandy Springs-Marietta, GA Barrow County, GA Bartow County, GA Butts County, GA Carroll County, GA Cherokee County, GA Clayton County, GA Cobb County, GA Coweta County, GA Dawson County, GA DeKalb County, GA Douglas County, GA Fayette County, GA Forsyth County, GA Fulton County, GA Gwinnett County, GA Haralson County, GA Heard County, GA Henry County, GA Jasper County, GA Lamar County, GA Meriwether County, GA Newton County, GA Paulding County, GA Pickens County, GA Pike County, GA Rockdale County, GA Spalding County, GA Walton County, GA	0.9549
12100	Atlantic City-Hammonton, NJ Atlantic County, NJ	1.1129
12220	Auburn-Opelika, AL Lee County, AL	0.7190
12260	Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC	0.9538
12420	Austin-Round Rock-San Marcos, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX	0.9514
12540	Bakersfield-Delano, CA Kern County, CA	1.1707
12580	Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD	1.0255
12620	Bangor, ME Penobscot County, ME	0.9777
12700	Barnstable Town, MA Barnstable County, MA	1.2823
12940	Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA	0.8583
12980	Battle Creek, MI Calhoun County, MI	0.9656
13020	Bay City, MI Bay County, MI	0.9221
13140	Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX	0.8488
13380	Bellingham, WA Whatcom County, WA	1.1390
13460	Bend, OR Deschutes County, OR	1.1372
13644	Bethesda-Rockville-Frederick, MD Frederick County, MD Montgomery County, MD	1.0525
13740	Billings, MT Carbon County, MT Yellowstone County, MT	0.8674
13780	Binghamton, NY Broome County, NY Tioga County, NY	0.8719

CBSA Code	Urban Area (Constituent Counties)	Wage Index
13820	Birmingham-Hoover, AL Bibb County, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL	0.8611
13900	Bismarck, ND Burleigh County, ND Morton County, ND	0.7348
13980	Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA	0.8314
14020	Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN	0.8989
14060	Bloomington-Normal, IL McLean County, IL	0.9439
14260	Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID	0.9273
14484	Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA	1.2178
14500	Boulder, CO Boulder County, CO	1.0065
14540	Bowling Green, KY Edmonson County, KY Warren County, KY	0.8666
14740	Bremerton-Silverdale, WA Kitsap County, WA	1.0667
14860	Bridgeport-Stamford-Norwalk, CT Fairfield County, CT	1.2547
15180	Brownsville-Harlingen, TX Cameron County, TX	0.9173
15260	Brunswick, GA Brantley County, GA Glynn County, GA McIntosh County, GA	0.9209
15380	Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY	0.9530
15500	Burlington, NC Alamance County, NC	0.8863
15540	Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT	0.9947
15764	Cambridge-Newton-Framingham, MA Middlesex County, MA	1.1250
15804	Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ	1.0386
15940	Canton-Massillon, OH Carroll County, OH Stark County, OH	0.8749
15980	Cape Coral-Fort Myers, FL Lee County, FL	0.9195
16020	Cape Girardeau-Jackson, MO-IL Alexander County, IL Bollinger County, MO Cape Girardeau County, MO	0.8983
16180	Carson City, NV Carson City, NV	1.0465
16220	Casper, WY Natrona County, WY	0.9655
16300	Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA	0.8844
16580	Champaign-Urbana, IL Champaign County, IL Ford County, IL Piatt County, IL	1.0235
16620	Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV	0.7895

CBSA Code	Urban Area (Constituent Counties)	Wage Index
16700	Charleston-North Charleston-Summerville, SC Berkeley County, SC Charleston County, SC Dorchester County, SC	0.9354
16740	Charlotte-Gastonia-Rock Hill, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC	0.9420
16820	Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA	0.9342
16860	Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN	0.8829
16940	Cheyenne, WY Laramie County, WY	0.9392
16974	Chicago-Joliet-Naperville, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL	1.0593
17020	Chico, CA Butte County, CA	1.1533
17140	Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH	0.9699
17300	Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN	0.7888
17420	Cleveland, TN Bradley County, TN Polk County, TN	0.7731
17460	Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH	0.9050
17660	Coeur d'Alene, ID Kootenai County, ID	0.9364
17780	College Station-Bryan, TX Brazos County, TX Burleson County, TX Robertson County, TX	0.9588
17820	Colorado Springs, CO El Paso County, CO Teller County, CO	0.9481
17860	Columbia, MO Boone County, MO Howard County, MO	0.8282

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17900	Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC	0.8733
17980	Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscogee County, GA	0.9027
18020	Columbus, IN Bartholomew County, IN	0.9434
18140	Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH	1.0141
18580	Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX	0.8585
18700	Corvallis, OR Benton County, OR	1.0455
18880	Crestview-Fort Walton Beach-Destin, FL Okaloosa County, FL	0.8842
19060	Cumberland, MD-WV Allegany County, MD Mineral County, WV	0.8186
19124	Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX	0.9860
19140	Dalton, GA Murray County, GA Whitfield County, GA	0.8622
19180	Danville, IL Vermilion County, IL	0.9693
19260	Danville, VA Pittsylvania County, VA Danville City, VA	0.8168
19340	Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA	0.8400
19380	Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH	0.9140
19460	Decatur, AL Lawrence County, AL Morgan County, AL	0.7621
19500	Decatur, IL Macon County, IL	0.7916
19660	Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL	0.8736
19740	Denver-Aurora-Broomfield, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO	1.0718
19780	Des Moines-West Des Moines, IA Dallas County, IA Guthrie County, IA Madison County, IA Polk County, IA Warren County, IA	0.9621
19804	Detroit-Livonia-Dearborn, MI Wayne County, MI	0.9699

CBSA Code	Urban Area (Constituent Counties)	Wage Index
20020	Dothan, AL Geneva County, AL Henry County, AL Houston County, AL	0.7435
20100	Dover, DE Kent County, DE	0.9921
20220	Dubuque, IA Dubuque County, IA	0.8774
20260	Duluth, MN-WI Carlton County, MN St. Louis County, MN Douglas County, WI	1.0565
20500	Durham-Chapel Hill, NC Chatham County, NC Durham County, NC Orange County, NC Person County, NC	0.9664
20740	Eau Claire, WI Chippewa County, WI Eau Claire County, WI	0.9639
20764	Edison-New Brunswick, NJ Middlesex County, NJ Monmouth County, NJ Ocean County, NJ Somerset County, NJ	1.1006
20940	El Centro, CA Imperial County, CA	0.9258
21060	Elizabethtown, KY Hardin County, KY Larue County, KY	0.8449
21140	Elkhart-Goshen, IN Elkhart County, IN	0.9465
21300	Elmira, NY Chemung County, NY	0.8445
21340	El Paso, TX El Paso County, TX	0.8475
21500	Erie, PA Erie County, PA	0.8360
21660	Eugene-Springfield, OR Lane County, OR	1.1384
21780	Evansville, IN-KY Gibson County, IN Posey County, IN Vanderburgh County, IN Warrick County, IN Henderson County, KY Webster County, KY	0.8433
21820	Fairbanks, AK Fairbanks North Star Borough, AK	1.1080
21940	Fajardo, PR Ceiba Municipio, PR Fajardo Municipio, PR Luquillo Municipio, PR	0.3883
22020	Fargo, ND-MN Clay County, MN Cass County, ND	0.8064
22140	Farmington, NM San Juan County, NM	0.9339
22180	Fayetteville, NC Cumberland County, NC Hoke County, NC	0.9323
22220	Fayetteville-Springdale-Rogers, AR-MO Benton County, AR Madison County, AR Washington County, AR McDonald County, MO	0.8616
22380	Flagstaff, AZ Coconino County, AZ	1.2443
22420	Flint, MI Genesee County, MI	1.1496
22500	Florence, SC Darlington County, SC Florence County, SC	0.8252
22520	Florence-Muscle Shoals, AL Colbert County, AL Lauderdale County, AL	0.8144
22540	Fond du Lac, WI Fond du Lac County, WI	0.9223
22660	Fort Collins-Loveland, CO Larimer County, CO	0.9892
22744	Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL	1.0160

CBSA Code	Urban Area (Constituent Counties)	Wage Index
22900	Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Sequoyah County, OK	0.7599
23060	Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN	0.9362
23104	Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX	0.9474
23420	Fresno, CA Fresno County, CA	1.1422
23460	Gadsden, AL Etowah County, AL	0.7180
23540	Gainesville, FL Alachua County, FL Gilchrist County, FL	0.9160
23580	Gainesville, GA Hall County, GA	0.9223
23844	Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN	0.9084
24020	Glens Falls, NY Warren County, NY Washington County, NY	0.8507
24140	Goldsboro, NC Wayne County, NC	0.9067
24220	Grand Forks, ND-MN Polk County, MN Grand Forks County, ND	0.7717
24300	Grand Junction, CO Mesa County, CO	0.9850
24340	Grand Rapids-Wyoming, MI Barry County, MI Ionia County, MI Kent County, MI Newaygo County, MI	0.9169
24500	Great Falls, MT Cascade County, MT	0.8289
24540	Greeley, CO Weld County, CO	0.9496
24580	Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI	0.9586
24660	Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC	0.8882
24780	Greenville, NC Greene County, NC Pitt County, NC	0.9370
24860	Greenville-Mauldin-Easley, SC Greenville County, SC Laurens County, SC Pickens County, SC	0.9644
25020	Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR	0.3686
25060	Gulfport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS	0.8877
25180	Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV	0.9254
25260	Hanford-Corcoran, CA Kings County, CA	1.1205
25420	Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA	0.9296
25500	Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA	0.9158
25540	Hartford-West Hartford-East Hartford, CT Hartford County, CT Middlesex County, CT Tolland County, CT	1.0927
25620	Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS	0.7714

CBSA Code	Urban Area (Constituent Counties)	Wage Index
25860	Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC	0.8693
25980[1]	Hinesville-Fort Stewart, GA Liberty County, GA Long County, GA	0.8958
26100	Holland-Grand Haven, MI Ottawa County, MI	0.8632
26180	Honolulu, HI Honolulu County, HI	1.1807
26300	Hot Springs, AR Garland County, AR	0.9151
26380	Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA	0.7852
26420	Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX	0.9824
26580	Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV	0.8953
26620	Huntsville, AL Limestone County, AL Madison County, AL	0.9191
26820	Idaho Falls, ID Bonneville County, ID Jefferson County, ID	0.9663
26900	Indianapolis-Carmel, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN	0.9672
26980	Iowa City, IA Johnson County, IA Washington County, IA	0.9657
27060	Ithaca, NY Tompkins County, NY	0.9842
27100	Jackson, MI Jackson County, MI	0.9155
27140	Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS	0.8042
27180	Jackson, TN Chester County, TN Madison County, TN	0.8404
27260	Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL	0.8884
27340	Jacksonville, NC Onslow County, NC	0.7807
27500	Janesville, WI Rock County, WI	0.9415
27620	Jefferson City, MO Callaway County, MO Cole County, MO Moniteau County, MO Osage County, MO	0.8434
27740	Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN	0.8105

CBSA Code	Urban Area (Constituent Counties)	Wage Index
27780	Johnstown, PA Cambria County, PA	0.8090
27860	Jonesboro, AR Craighead County, AR Poinsett County, AR	0.7757
27900	Joplin, MO Jasper County, MO Newton County, MO	0.8214
28020	Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI	1.0292
28100	Kankakee-Bradley, IL Kankakee County, IL	1.0619
28140	Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO	0.9652
28420	Kennewick-Pasco-Richland, WA Benton County, WA Franklin County, WA	0.9976
28660	Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX	0.8798
28700	Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA	0.7588
28740	Kingston, NY Ulster County, NY	0.9075
28940	Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN	0.7842
29020	Kokomo, IN Howard County, IN Tipton County, IN	0.9130
29100	La Crosse, WI-MN Houston County, MN La Crosse County, WI	0.9803
29140	Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN	0.9289
29180	Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA	0.8489
29340	Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA	0.8196
29404	Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI	1.0781
29420	Lake Havasu City-Kingman, AZ Mohave County, AZ	1.0235
29460	Lakeland-Winter Haven, FL Polk County, FL	0.8447
29540	Lancaster, PA Lancaster County, PA	0.9344
29620	Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI	1.0298
29700	Laredo, TX Webb County, TX	0.7914
29740	Las Cruces, NM Dona Ana County, NM	0.9296
29820	Las Vegas-Paradise, NV Clark County, NV	1.2099
29940	Lawrence, KS Douglas County, KS	0.8533
30020	Lawton, OK Comanche County, OK	0.8285

CBSA Code	Urban Area (Constituent Counties)	Wage Index
30140	Lebanon, PA Lebanon County, PA	0.7807
30300	Lewiston, ID-WA Nez Perce County, ID Asotin County, WA	0.9358
30340	Lewiston-Auburn, ME Androscoggin County, ME	0.8903
30460	Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY	0.8817
30620	Lima, OH Allen County, OH	0.9271
30700	Lincoln, NE Lancaster County, NE Seward County, NE	0.9617
30780	Little Rock-North Little Rock-Conway, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR	0.8546
30860	Logan, UT-ID Franklin County, ID Cache County, UT	0.8794
30980	Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX	0.8563
31020	Longview, WA Cowlitz County, WA	1.0296
31084	Los Angeles-Long Beach-Glendale, CA Los Angeles County, CA	1.2130
31140	Louisville-Jefferson County, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Jefferson County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY	0.8896
31180	Lubbock, TX Crosby County, TX Lubbock County, TX	0.8847
31340	Lynchburg, VA Amherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA	0.8694
31420	Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA	0.9202
31460	Madera-Chowchilla, CA Madera County, CA	0.7986
31540	Madison, WI Columbia County, WI Dane County, WI Iowa County, WI	1.1294
31700	Manchester-Nashua, NH Hillsborough County, NH	0.9869
31740	Manhattan, KS Geary County, KS Pottawatomie County, KS Riley County, KS	0.7847
31860	Mankato-North Mankato, MN Blue Earth County, MN Nicollet County, MN	0.9083

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31900	Mansfield, OH Richland County, OH	0.8918
32420	Mayagüez, PR Hormigueros Municipio, PR Mayagüez Municipio, PR	0.3640
32580	McAllen-Edinburg-Mission, TX Hidalgo County, TX	0.8837
32780	Medford, OR Jackson County, OR	1.0061
32820	Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN	0.9268
32900	Merced, CA Merced County, CA	1.2359
33124	Miami-Miami Beach-Kendall, FL Miami-Dade County, FL	1.0128
33140	Michigan City-La Porte, IN LaPorte County, IN	0.9470
33260	Midland, TX Midland County, TX	0.9711
33340	Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI	1.0183
33460	Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI	1.1143
33540	Missoula, MT Missoula County, MT	0.8921
33660	Mobile, AL Mobile County, AL	0.7960
33700	Modesto, CA Stanislaus County, CA	1.2104
33740	Monroe, LA Ouachita Parish, LA Union Parish, LA	0.7993
33780	Monroe, MI Monroe County, MI	0.8684
33860	Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL	0.8442
34060	Morgantown, WV Monongalia County, WV Preston County, WV	0.8137
34100	Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN	0.7041
34580	Mount Vernon-Anacortes, WA Skagit County, WA	1.0363
34620	Muncie, IN Delaware County, IN	0.8206
34740	Muskegon-Norton Shores, MI Muskegon County, MI	0.9809
34820	Myrtle Beach-North Myrtle Beach-Conway, SC Horry County, SC	0.8738

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34900	Napa, CA Napa County, CA	1.4604
34940	Naples-Marco Island, FL Collier County, FL	0.9698
34980	Nashville-Davidson–Murfreesboro-Franklin, TN Cannon County, TN Cheatham County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN	0.9457
35004	Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY	1.2315
35084	Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA	1.1460
35300	New Haven-Milford, CT New Haven County, CT	1.1515
35380	New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA	0.9070
35644	New York-White Plains-Wayne, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY	1.2955
35660	Niles-Benton Harbor, MI Berrien County, MI	0.8872
35840	North Port-Bradenton-Sarasota, FL Manatee County, FL Sarasota County, FL	0.9481
35980	Norwich-New London, CT New London County, CT	1.1215
36084	Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA	1.6354
36100	Ocala, FL Marion County, FL	0.8468
36140	Ocean City, NJ Cape May County, NJ	1.0879
36220	Odessa, TX Ector County, TX	0.9436
36260	Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT	0.9267
36420	Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McClain County, OK Oklahoma County, OK	0.8877
36500	Olympia, WA Thurston County, WA	1.1269

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36540	Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sarpy County, NE Saunders County, NE Washington County, NE	0.9583
36740	Orlando-Kissimmee-Sanford, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL	0.9163
36780	Oshkosh-Neenah, WI Winnebago County, WI	0.9566
36980	Owensboro, KY Daviess County, KY Hancock County, KY McLean County, KY	0.8370
37100	Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA	1.2377
37340	Palm Bay-Melbourne-Titusville, FL Brevard County, FL	0.9211
37380	Palm Coast, FL Flagler County, FL	0.8405
37460	Panama City-Lynn Haven-Panama City Beach, FL Bay County, FL	0.7954
37620	Parkersburg-Marietta-Vienna, WV-OH Washington County, OH Pleasants County, WV Wirt County, WV Wood County, WV	0.7455
37700	Pascagoula, MS George County, MS Jackson County, MS	0.8299
37764	Peabody, MA Essex County, MA	1.0979
37860	Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL	0.8254
37900	Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL	0.9149
37964	Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA Philadelphia County, PA	1.0803
38060	Phoenix-Mesa-Glendale, AZ Maricopa County, AZ Pinal County, AZ	1.0642
38220	Pine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR	0.8012
38300	Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA	0.8605
38340	Pittsfield, MA Berkshire County, MA	1.0371
38540	Pocatello, ID Bannock County, ID Power County, ID	0.9507
38660	Ponce, PR Juana Díaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR	0.4326
38860	Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME	0.9899

CBSA Code	Urban Area (Constituent Counties)	Wage Index
38900	Portland-Vancouver-Hillsboro, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA	1.1476
38940	Port St. Lucie, FL Martin County, FL St. Lucie County, FL	1.0723
39100	Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY	1.1354
39140	Prescott, AZ Yavapai County, AZ	1.2234
39300	Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI	1.0714
39340	Provo-Orem, UT Juab County, UT Utah County, UT	0.9321
39380	Pueblo, CO Pueblo County, CO	0.8721
39460	Punta Gorda, FL Charlotte County, FL	0.8759
39540	Racine, WI Racine County, WI	1.0580
39580	Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC	0.9811
39660	Rapid City, SD Meade County, SD Pennington County, SD	1.0442
39740	Reading, PA Berks County, PA	0.8904
39820	Redding, CA Shasta County, CA	1.4134
39900	Reno-Sparks, NV Storey County, NV Washoe County, NV	1.0419
40060	Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Chesterfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA	0.9661
40140	Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA	1.1570
40220	Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA	0.8827
40340	Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN	1.0942
40380	Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY	0.8595
40420	Rockford, IL Boone County, IL Winnebago County, IL	1.0033
40484	Rockingham County-Strafford County, NH Rockingham County, NH	1.0026

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	Strafford County, NH	
40580	Rocky Mount, NC Edgecombe County, NC Nash County, NC	0.9034
40660	Rome, GA Floyd County, GA	0.8635
40900	Sacramento--Arden-Arcade--Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA	1.4053
40980	Saginaw-Saginaw Township North, MI Saginaw County, MI	0.8728
41060	St. Cloud, MN Benton County, MN Stearns County, MN	1.1042
41100	St. George, UT Washington County, UT	0.9133
41140	St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO	1.0302
41180	St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO	0.9090
41420	Salem, OR Marion County, OR Polk County, OR	1.1133
41500	Salinas, CA Monterey County, CA	1.5686
41540	Salisbury, MD Somerset County, MD Wicomico County, MD	0.9005
41620	Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT	0.9266
41660	San Angelo, TX Irion County, TX Tom Green County, TX	0.8303
41700	San Antonio-New Braunfels, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX	0.8998
41740	San Diego-Carlsbad-San Marcos, CA San Diego County, CA	1.1979
41780	Sandusky, OH Erie County, OH	0.8686
41884	San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA	1.5733
41900	San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR	0.4560
41940	San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA	1.6703

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41980	San Juan-Caguas-Guaynabo, PR Aguas Buenas Municipio, PR Aibonito Municipio, PR Arecibo Municipio, PR Barceloneta Municipio, PR Barranquitas Municipio, PR Bayamón Municipio, PR Caguas Municipio, PR Camuy Municipio, PR Canóvanas Municipio, PR Carolina Municipio, PR Cataño Municipio, PR Cayey Municipio, PR Ciales Municipio, PR Cidra Municipio, PR Comerío Municipio, PR Corozal Municipio, PR Dorado Municipio, PR Florida Municipio, PR Guaynabo Municipio, PR Gurabo Municipio, PR Hatillo Municipio, PR Humacao Municipio, PR Juncos Municipio, PR Las Piedras Municipio, PR Loíza Municipio, PR Manatí Municipio, PR Maunabo Municipio, PR Morovis Municipio, PR Naguabo Municipio, PR Naranjito Municipio, PR Orocovis Municipio, PR Quebradillas Municipio, PR Río Grande Municipio, PR San Juan Municipio, PR San Lorenzo Municipio, PR Toa Alta Municipio, PR Toa Baja Municipio, PR Trujillo Alto Municipio, PR Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR	0.4296
42020	San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA	1.2915
42044	Santa Ana-Anaheim-Irvine, CA Orange County, CA	1.2162
42060	Santa Barbara-Santa Maria-Goleta, CA Santa Barbara County, CA	1.1909
42100	Santa Cruz-Watsonville, CA Santa Cruz County, CA	1.6740
42140	Santa Fe, NM Santa Fe County, NM	1.0847
42220	Santa Rosa-Petaluma, CA Sonoma County, CA	1.6143
42340	Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA	0.8907
42540	Scranton--Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA	0.8238
42644	Seattle-Bellevue-Everett, WA King County, WA Snohomish County, WA	1.1556
42680	Sebastian-Vero Beach, FL Indian River County, FL	0.9097
43100	Sheboygan, WI Sheboygan County, WI	0.9233
43300	Sherman-Denison, TX Grayson County, TX	0.8279
43340	Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA	0.8536
43580	Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD	0.9091
43620	Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD	0.9299
43780	South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI	0.9948
43900	Spartanburg, SC Spartanburg County, SC	0.9383
44060	Spokane, WA Spokane County, WA	1.0571

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44100	Springfield, IL Menard County, IL Sangamon County, IL	0.9130
44140	Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA	1.0251
44180	Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO	0.8371
44220	Springfield, OH Clark County, OH	0.9234
44300	State College, PA Centre County, PA	0.8779
44600	Steubenville-Weirton, OH-WV Jefferson County, OH Brooke County, WV Hancock County, WV	0.7315
44700	Stockton, CA San Joaquin County, CA	1.2644
44940	Sumter, SC Sumter County, SC	0.7860
45060	Syracuse, NY Madison County, NY Onondaga County, NY Oswego County, NY	0.9905
45104	Tacoma, WA Pierce County, WA	1.1343
45220	Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL Wakulla County, FL	0.8806
45300	Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL	0.9054
45460	Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN	0.9205
45500	Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX	0.7748
45780	Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH	0.9432
45820	Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS	0.8952
45940	Trenton-Ewing, NJ Mercer County, NJ	1.0150
46060	Tucson, AZ Pima County, AZ	0.9480
46140	Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK	0.8793
46220	Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL	0.8843
46340	Tyler, TX Smith County, TX	0.8065
46540	Utica-Rome, NY Herkimer County, NY Oneida County, NY	0.8471
46660	Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA	0.7941

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46700	Vallejo-Fairfield, CA Solano County, CA	1.4931
47020	Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX	0.8219
47220	Vineland-Millville-Bridgeton, NJ Cumberland County, NJ	1.0534
47260	Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surry County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA	0.8961
47300	Visalia-Porterville, CA Tulare County, CA	1.0738
47380	Waco, TX McLennan County, TX	0.8403
47580	Warner Robins, GA Houston County, GA	0.8028
47644	Warren-Troy-Farmington Hills, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI	0.9648
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV	1.0723
47940	Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA	0.8462
48140	Wausau, WI Marathon County, WI	0.9563
48300	Wenatchee-East Wenatchee, WA Chelan County, WA Douglas County, WA	0.9615
48424	West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL	0.9934
48540	Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV	0.6675
48620	Wichita, KS Butler County, KS Harvey County, KS Sedgwick County, KS Sumner County, KS	0.8898
48660	Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX	0.9566

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48700	Williamsport, PA Lycoming County, PA	0.7256
48864	Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ	1.0580
48900	Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC	0.9202
49020	Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV	1.0002
49180	Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC	0.8939
49340	Worcester, MA Worcester County, MA	1.1012
49420	Yakima, WA Yakima County, WA	1.0067
49500	Yauco, PR Guánica Municipio, PR Guayanilla Municipio, PR Peñuelas Municipio, PR Yauco Municipio, PR	0.3536
49620	York-Hanover, PA York County, PA	0.9983
49660	Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA	0.8625
49700	Yuba City, CA Sutter County, CA Yuba County, CA	1.1043
49740	Yuma, AZ Yuma County, AZ	0.9283

[1] At this time, there are no hospitals in these urban areas on which to base a wage index. Therefore, the urban wage index value is based on the average wage index of all urban areas within the State.

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