

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

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**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.

EFFECTIVE DATE: These regulations are effective on January 1, 2011.

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

the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) the computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage 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 a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

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

implement the pay-for-reporting requirement of the DRA, which was codified at §484.225(h) and (i) in accordance with the statute.

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

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS 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	40 th	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 does 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 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 comorbid 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 assure 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 a 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 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 were 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 HHA's 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 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 that the commenter that the coverage criteria clarifications are consistent with statute, current regulations, and long-standing 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 long-standing manual guidance at 40.2.2 E. in chapter 7 of the Medicare Benefit Policy Manual, CMS Pub. 100-2. This section contains long-standing 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 long-standing 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 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 provide 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

