AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 76 Friday,
No. 214 November 4, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, and 484
Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, and 484

[CMS–1353–F]

RIN 0938–AQ30

Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012

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

ACTION: Final rule.

SUMMARY: This final rule sets forth updates to the home health prospective payment system (HH PPS) rates, including: the national standardized 60-day episode rates; the national per-visit rates; and the low utilization payment amount (LUPA) under the Medicare PPS for home health agencies effective January 1, 2012. This rule applies a 1.4 percent update factor to the episode rates, which reflects a 1 percent reduction applied to the 2.4 percent market basket update factor, as mandated by the Affordable Care Act. This rule also updates the wage index used under the HH PPS, and further reduces home health payments to account for continued nominal growth in case-mix which is unrelated to changes in patient health status. This rule removes two hypertension codes from the HH PPS case-mix system, thereby requiring recalibration of the case-mix weights. In addition, the rule implements two structural changes designed to decrease incentives to upcode and provide unneeded therapy services. Finally, this rule incorporates additional flexibility regarding face-to-face encounters with providers related to home health care.

DATES: *Effective Date:* These regulations are effective on January 1, 2012.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Goldstein, (410) 786–6665, for CAHPS issues.
Mary Pratt, (410) 786–6867, for quality issues.
Randy Throndset, (410) 786–0131 (overall HH PPS).

Table of Contents

I. Background
A. Statutory Background
B. System for Payment of Home Health Services
C. Updates to the HH PPS
II. Provisions of the Proposed Rule and Response to Comments
A. Case-Mix Measurement
B. Case-Mix Revision to the Case-Mix Weights
1. Hypertension Diagnosis Coding Under the HH PPS
2. Revision of the Case-Mix Weights
C. Outlier Policy
1. Background
2. Comments and Responses
D. CY 2012 Rate Update
1. Home Health Market Basket Update
2. Home Health Care Quality Reporting Program
a. Background and Quality Reporting Requirements
b. OASIS Data
c. Claims Data, Requirements and Outcome Measure Change
d. Home Health Care CAHPS Survey (HHCAHPS)
3. Home Health Wage Index
4. CY 2012 Annual Payment Update
a. National Standardized 60-Day Episode Rate
b. Updated CY 2012 National Standardized 60-Day Episode Payment Rate
c. National Per-Visit Rates Used To Pay LUPAs and Compute Imputed Costs Used in Outlier Calculations
d. LUPA Add-On Payment Amount Update
e. Nonroutine Medical Supply Conversion Factor Update
5. Rural Add-On
E. Therapy Corrections and Clarification
F. Home Health Face-to-Face Encounter
G. Payment Reform: Home Health Study and Report
H. International Classification of Diseases 10th Edition (ICD–10) Coding
I. Clarification to Benefit Policy Manual Language on ''Confined to the Home'' Definition
III. Collection of Information Requirements
IV. Regulatory Impact Analysis
V. Federalism Analysis
Regulations Text

Acronyms

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

ADL Activities of daily living
APA Administrative Procedures Act
APU Annual payment update
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
CR Cost report
CBSA Core-based statistical area
CBO Congressional Budget Office
CMI Case-mix index
CMS Centers for Medicare and Medicaid Services
CoPs Conditions of participation
DRA Deficit Reduction Act of 2005, Public Law 109–171, enacted February 8, 2006
FDL Fixed dollar loss
FI Fiscal intermediaries
FR Federal Register
FY Fiscal year
HCC Hierarchical condition categories
HCIS Health Care Information System
HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHAs Home health agencies
HHRG Home health resource group
HIPPS Health Insurance Prospective Payment System
IRF Inpatient Rehabilitation Facility
LTCH Long-Term Care Hospital
LUPA Low Utilization Payment Amount
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, enacted December 8, 2003
MSA Metropolitan statistical area
MSS Medical social services
NAHC National Association for Home Care and Hospice
NHLBI National Heart Lung and Blood Institute
NPP Nonphysician practitioner
NRS Non-routine supplies
OBRA Omnibus Reconciliation Act of 1981, Public Law 97–35, enacted August 13, 1981
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Public Law 105–277, enacted October 21, 1998
OES Occupational employment statistics
OIG Office of Inspector General
OT Occupational therapy
OMB Office of Management and Budget
PEP Partial episode payment
POC Plan of care
PT Physical therapy
QAP Quality assurance plan
PRRB Provider Reimbursement Review Board
RAP Request for anticipated payment
RFA Regulatory Flexibility Act, Public Law 96–354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
SLP Speech Language Pathology Therapy
SNF Skilled Nursing Facility
UMRA Unfunded Mandates Reform Act of 1995

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare 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 (CR) data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

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

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

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 3131(b) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that estimated 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 section 4603(a) of the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

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

Section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003) provides an increase of 3 percent of the payment amount otherwise made under section 1886(d)(2)(D) of the Act for HH services furnished in a rural area for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine 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 II.D.4.e). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode.

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

C. Updates to the HH PPS

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HHAs for CY 2008. The CY 2008 rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. 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 expenditures to predict the average case-mix weight for 2005. We identified

8.03 percent of the total case-mix change as real and decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent (0.1278 * (1 − 0.0803) = 0.1175).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction over 4 years in the national standardized 60-day episode payment rates 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.

For CY 2011, we published the November 17, 2010 final rule (75 FR 70372) (hereinafter referred to as the CY 2011 HH PPS final rule) that set forth the update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HH services.

As discussed in the CY 2011 HH PPS final rule, our analysis indicated that there was a 19.40 percent increase in overall case-mix from 2000 to 2008 and that only 10.07 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 17.45 percent nominal increase in case-mix. To fully account for the 17.45 percent nominal case-mix growth which was identified from 2000 to 2008, we proposed 3.79 percent payment reductions in both CY 2011 and CY 2012. However, we deferred finalizing a payment reduction for CY 2012 until a further study of the case-mix data was completed. Independent review of the case-mix model has been conducted and the results were discussed in section II.A. of the proposed rule, which was issued on July 12, 2011 (76 FR 40988).

II. Provisions of the Proposed Rule and Response to Comments

A. Case-Mix Measurement

As stated in the proposed rule issued in the July 12, 2011 **Federal Register**, every year, since the HH PPS CY 2008 proposed rule, we have stated in HH PPS rulemaking that we would continue to monitor case-mix changes in the HH PPS and to update our analysis to measure change in case-mix, both real changes in case-mix and changes which are unrelated to changes in patient acuity (nominal). We have continued to monitor case-mix changes and our latest analysis continues to support the need to make payment adjustments to account for nominal case-mix growth.

In the CY 2012 HH PPS proposed rule (76 FR 40991), we also stated that in response to comments we received on our case-mix measurement methodology during CY 2011 rulemaking, we procured an independent review of our methodology by a team at Harvard University led by Dr. David Grabowski. The review included an examination of the predictive regression models and data used in CY 2011 rulemaking, and further analysis consisting of extensions of the model to allow a closer look at nominal case-mix growth by categorizing the growth according to provider types and subgroups of patients. The extensions showed a similar rate of nominal case-mix growth from 2000 to 2008 for the various categories and subgroups. In addition, when reviewing the model, the Harvard team found that overall, our models are robust. However, one area of potential refinement to our models that the Harvard team suggested was to incorporate variables derived from Hierarchical Condition Categories (HCC) data, which is used by CMS to risk-adjust payments to managed care organizations in the Medicare program.

Based on Dr. Grabowski and his team's recommendation and our previous consideration to incorporate HCC data in our models to assess real case-mix change, we decided to explore the effects of adding HCC patient classification data into our models. For our analysis of real and nominal case-mix growth from 2000 to 2009, we incorporated the HCC community scores, HCC demographic variables, and disease indicator variables into our models.

In addition, for our analysis, we used a similar approach to our previous methods. The basic method is to estimate a prediction model and use coefficients from that model along with predictor variables from a different year to predict the average case-mix for that year. It should be noted that we chose to enhance our models with HCC data starting in 2005 due to the availability of HCC data in our analytic files. Therefore, we analyzed real case-mix change for 3 different periods, from 2000 to 2005, from 2005 to 2007, and from 2007 to 2009. The real case-mix change from 2000 to 2005 was assessed using the same variables used in the model described in last year's regulation (75 FR 43238). The real case-mix change from 2005 to 2007 and from 2007 to 2009 was assessed using additional information from the HCC variables. To determine the amount of real and nominal case-mix change from 2000 to 2009, we added the change in case-mix units for each of the 3 periods and compared it to the total change in case-mix from 2000 to 2009. Based on the results from our models, we estimated 15.76 percent of the total case-mix change as real. When taking into account the total case-mix change from 2000 to 2009 (22.59 percent) and the 15.76 percent of total case-mix change estimated as real from 2000 to 2009, we obtained a final nominal case-mix change measure of 19.03 percent from 2000 to 2009 (0.2259 * (1 − 0.1576) = 0.1903).

In each of the years 2008, 2009, and 2010, we reduced payment rates by 2.75 percent and in 2011 we reduced payment rates by 3.79 percent to account for nominal case-mix change from 2000. In the proposed rule, we stated that a payment reduction of 5.06 percent would be needed to account for the outstanding amount of nominal case-mix change we estimated based on the real case-mix change analysis updated through 2009 and we proposed to implement a 5.06 percent reduction to the national standardized 60-day episode rates to account for the entire residual amount of nominal case-mix change through 2009 in one year.

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

Comment: Some commenters stated that CMS should not implement an across-the-board punishment but rather target the agencies that have high nominal case-mix growth. Other commenters stated that all home health providers should not be punished for the actions of the few. Many commenters indicated that their agency had case-mix weights below the national average and some commenters stated that there has been a decline in their case-mix over the years. Commenters suggested that CMS limit the case-mix reductions to certain agencies and only apply the reduction to agencies whose average case-mix weight reflects high nominal case-mix growth.

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. When performing an independent review of

our case-mix measurement methodology, Dr. Grabowski and his team at Harvard University agreed with our reasons for not proposing targeted reductions, stating their concerns about the small sample size of many agencies and their findings of significant nominal case-mix across different classes of agencies (please see the report located at *https://www.cms.gov/center/hha.asp)*.

We note that although we have stated in past regulations that a targeted system would be administratively burdensome, the reasons we have just presented go beyond administrative complexity. Certain comments seem to assume that 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 not the level of case-mix reached over a period of time, but the amount of change in the billed case-mix weights not attributable to underlying changes in actual patient severity.

In addition, in this final rule, we are finalizing a revision to the case-mix weights. As described in Section II.B., we are removing two hypertension codes from our case-mix system which are not associated with additional resource use and we are reducing weights for episodes with high therapy while increasing weights for episodes with no or low therapy. This revision to the case-mix weights should slow future nominal case-mix growth and provide a more targeted approach for addressing overpayment of services, while also improving the accuracy of the HH PPS.

Comment: Some commenters stated that the payment cuts will make it difficult for small agencies to exist, leaving a market that will only be made up of large for-profit agencies. Other commenters stated that from 2000 to 2008, for-profit and free-standing agencies saw their nominal case-mix grow by approximately 3.5 percent to 4.0 percent more than non-profit, government-owned and facility-based agencies. Commenters attributed the difference in nominal case-mix growth to the idea that for-profit agencies ''pick and choose'' their patients while non-profit and government agencies tend to serve all patients needing home health care. Commenters requested that CMS either forego the proposed 5.06 percent adjustment or implement a two-tiered adjustment factor, with a much lower payment reduction factor for non-profit, government-owned and facility-based agencies.

Response: When looking at the case-mix growth by agency type, our data shows high case-mix growth across all agency types. While for-profit agencies' case-mix grew approximately 22.7 percent, the case-mix average for non-profit agencies and government agencies also grew considerably (17.8 percent and 17.5 percent). In addition, agencies with less than 99 episodes had a case-mix growth of 20.1 percent from 2000 to 2009 and agencies with 100 or more episodes had a case-mix growth of 24.8 percent from 2000 to 2009. These differences are not large enough to warrant a tiered approach. 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.

In addition, we acknowledge that our analyses and the analysis conducted by the Harvard team revealed a difference in nominal case-mix growth between for-profit agencies and non-profit/government agencies, as cited by the commenter. However, all categories exhibited a large amount of nominal case-mix growth, and differences among categories were not large enough to warrant a tiered approach. In view of that fact, making separate adjustments according to ownership category is inadvisable because of concerns about equity and administrative feasibility. We will continue to analyze the HH PPS to determine where it may inadvertently incentivize the sort of selective admissions which a commenter described and we will continue to analyze how we can strengthen the HH PPS to increase payment accuracy while mitigating risks which would incentivize such selective admissions.

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: 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 home health 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. In addition, we refer the commenters to section IV where we describe the impact of the provisions of this rule, including the revision of the case-mix weights. Section IV shows that when taking into account all of the provisions in this final rule, non-profit providers should experience less of a negative impact than for-profit providers. Also, in section IV, we describe our rationale why we believe access to Medicare home health will not be adversely affected by our policies, including the payment reductions.

Comment: Commenters stated that by implementing an across the board payment cut, agencies who have been more profitable may survive while agencies that have smaller margins may fail, thus potentially preserving those who may be committing abuse.

Response: Existing information about Medicare margins and the CR data we have analyzed suggest that most agencies will continue to have positive margins on their Medicare business. With our revisions to the case-mix weights, we expect the weight adjustments will reduce the incentive to provide more therapy than is clinically indicated. To the extent that profits are based on abusive behavior, we believe these changes will mitigate the risks of abusive behavior. We also believe the changes will result in more equitable revenues and profits.

Comment: Commenters stated that they believe that the case-mix measurement methodology takes on the approach that all case-mix change is nominal unless it can be proved otherwise.

Response: The evidence for nominal case-mix change is based on the small amount of change in patients' characteristics generally, as measured by patient demographics and information from the National Claims History on home health patients. We summarized the change in patients' characteristics in terms of the impact on the average case-mix weight. In this analysis, the remainder of the change in

average case-mix weights is unexplained, and it is generally believed that coding change is responsible. Our method to assess real and nominal case-mix change is the most effective method available to us at this time. We remind the commenter that we have presented various types of other data in previous rulemaking consistent with the model-based evidence indicating that home health care patients have not changed much since the last 12 months of the Interim Payment System.

Comment: A commenter suggested that CMS ''adjust out all data from active and closed settlement actions'' in their measurement of real and nominal case-mix growth.

Response: We are unclear what the commenter is suggesting. As we have noted previously, nominal case-mix growth is an across the board issue. If the commenter is referring to recoupments which correspond to claims denied after they were reviewed, such would typically be reflected in the claims data we use in our case mix analysis. In the case where a paid-claim dispute is still active, this data would likely not have much effect on our determination of nominal case-mix growth.

Comment: Commenters requested that CMS increase its program integrity efforts to combat fraud, waste, and abuse. Other commenters stated that instead of implementing a payment reduction, CMS should audit agencies that appear to be manipulating the case-mix system. 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: We have taken various measures to reduce payment vulnerabilities and the Federal government has launched actions to directly identify fraudulent and abusive activities. Commenters should be aware of tip lines available that can help support investigative efforts of the Federal government. The Office of the Inspector General, Department of Health and Human Services Web site at *http://oig.hhs.gov/fraud/report-fraud/index.asp,* provides information about how to report fraud. Another Web site, *http://www.stopmedicarefraud.gov/index.html,* is oriented to Medicare patients and their families and provides information about recognizing fraud.

In addition, while we appreciate the commenters' suggestion about the targeted claims review, we cannot perform targeted claim review as suggested, 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: A commenter stated that if the payment reduction is implemented, the base rate will be less than at the start of the HH PPS.

Response: When assessing the impact of the payment reductions, one must also consider the effects of the case-mix weights. Section 1895(b)(3)(B)(iv) of the Act requires that payment adjustments in response to nominal case-mix change be made to the rates. As such, we must reduce the base rate to account for growth in nominal case-mix. However, we note that we have not reduced the average case-mix weight and the average case-mix weight has increased since the beginning of the HH PPS. Therefore, even with the payment reductions to account for nominal case-mix growth since the beginning of the HH PPS, the average payment is projected to be higher for CY 2012 than the average payment at the beginning of the HH PPS.

Comment: Commenters mentioned the Affordable Care Act study which is investigating access to care issues and stated that the payment cuts will only further exacerbate access to care issues for vulnerable populations.

Response: We appreciate the commenter's concerns and wish to note that our preliminary analysis suggests that vulnerable populations are associated with case-mix groups involving lower levels of therapy, and that we have adjusted weights upward for those lower-therapy case-mix groups. For example, whereas the average number of therapy visits for first episodes overall is 8.2 in 2009, the average for vulnerable groups in various classifications (for example, high-poverty counties or rural areas) ranged between 7.0 and 7.8. The impact analysis of this rule indicates that rural agencies will experience a smaller reduction overall than urban agencies. We note that rural agencies will continue to receive a 3 percent payment add-on in CY 2012. We anticipate that these aspects of the payment proposals will mitigate the risk of access issues. We also wish to report that the Affordable Care Act study is proceeding as planned. It will involve additional data gathering on vulnerable populations and on potential access problems that vulnerable beneficiaries may encounter in coming years. We will continue to monitor for unintended consequences and we will seek information from other government agencies, such as the Office of the Inspector General, on access. Finally, we will use Open Door Forums and other venues to solicit information from agencies on any actual access issues they witness.

Comment: Commenters stated that the payment cuts will limit access to care and hinder the effort to move to more community-based care.

Response: We do not believe this will be the case because payment will remain adequate. Medicare has implemented policies to support community-based care in other areas, such as hospital-readmissions and transition programs authorized by the Affordable Care Act. We encourage HHAs to partner with providers in their community to become a part of these efforts, thereby assisting in the movement to more community-based care.

Comment: Commenters also thought that the payment reductions would lower quality of care.

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

Comment: Commenters were concerned that the proposed cuts would impede access to home health care because many agencies would be forced to close as a result of the lower payments. Commenters stated that if the proposed cuts are implemented, many providers will be operating at a negative or zero margins. A commenter stated that the reduction to payment rates along with other cuts mandated by the Affordable Care Act would cause over half of HHAs to be paid less than the cost of care to Medicare patients. This commenter provided a chart which forecasts 2012 profit margins for each State should the proposed 5.06 percent reduction to payments be finalized. The commenter further described that six States and Guam would have more than 70 percent of their agencies with negative margins in CY 2012 as a result of the reduction. Specifically, the commenter described the States and the

corresponding percent of HHAs which would be forced into negative margins as: Alaska 80 percent; Idaho 76.9 percent; North Dakota 91.7 percent; Oregon 96.2 percent; Vermont 70 percent; and Wisconsin 74.5 percent. Other commenters stated that the payment reductions place more of a hardship on certain providers. The commenters stated that rural locations would be hit the hardest. Commenters also stated that if the proposed cuts take place, over 45 percent of Minnesota providers will be operating at a zero or negative margin in 2012 and nearly 60 percent in 2017. Other commenters stated that the Northeast has a significantly lower rate of increase in case-mix growth than any other region. Commenters stated that the payment reductions will differentially impact different regions of the country and urged CMS to do a State-by-State analysis.

Response: As we have noted in prior rules, 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.

Regarding the commenters' concerns about the effect of the proposed reductions on providers' viability and the resultant access risks, we note that in their March 2011 Report to Congress, MedPAC projected an average of 14.5 percent margins for HHAs in 2011, when taking into account various payment adjustments such as the CY 2011 payment reduction for nominal case-mix growth. We also note that in proposing the reductions, we analyzed the combined effects of all of the policies proposed and believe that a 5.06 percent reduction would not impede access to care. We believe that the margin analysis study submitted by one of the commenters, which projected the impact of the proposed policies on HHAs on a State-by-State basis, failed to take into account the effects of all of the policies in the rule. The payment reduction to the base rate is not the only policy affecting payment to HHAs described in the proposed rule. The effects of the payment update, wage index update and revision of case-mix weights also need to be taken into account when assessing the impact of the proposed provisions. We also believe that the commenter may have attempted to factor potential future reductions to HH PPS payments into the 2012 margin forecast. While the Affordable Care Act calls for CMS to rebase home health payments beginning in 2014 and apply a productivity adjustment to the yearly inflation increases beginning in 2015, the impact of these provisions would be impossible to accurately project at this time. Additionally, provisions that are targeted for implementation in 2014 and later would have no effect on CY 2012 provider margins. The following discussion describes the impact if we were to implement a 5.06 percent payment reduction in CY 2012, taking into account all of the policies in the rule. In the aggregate, HHAs would receive 3.52 percent less in payments in CY 2012 when compared to CY 2011 payments, reflecting the net effect of a 1.4 percent HH PPS payment update increase, a 0.03 percent payment increase resulting from the wage index update, and a 5.06 percent reduction in payments to account for nominal case-mix growth. We note that not all providers would experience a net 3.52 percent reduction in their payments if a 5.06 percent reduction in payments was finalized for CY 2012. As we described in the proposed rule and describe in this final rule, the revision of the case-mix weights would have a re-distributional effect which benefits rural and non-profit providers, and providers in certain areas of the country. For example, in aggregate, if a 5.06 percent reduction in payments was implemented for CY 2012, non-profit free-standing providers would experience an estimated 0.91 percent reduction and for-profit free-standing providers would experience an estimated 4.72 percent reduction in payments. Rural providers would fare better than urban providers, as rural non-profit freestanding providers would see an estimated 0.31 percent increase in payments. In response to the commenter who was concerned about providers in the Northeast, we note that New England providers are in an area of the country which would benefit from the re-distributional effects of the recalibration. On average, New England providers would experience an increase in payments in CY 2012.

We note that of the six States which the commenter contends would have 70 percent or more providers experiencing negative margins as a result of the payment reductions, five are in areas of the country which would benefit from the re-distributional effect of the case-mix weight revisions. In Table 1, we provide the estimated impact if we were to finalize a 5.06 percent payment reduction with the other policies in this final rule for purposes of addressing this comment.

TABLE 1: Impacts if a 5.06 percent payment reduction were implemented

U.S. State/ Territory	Impact in CY 2012 with a 5.06 percent payment reduction
Alaska	-0.81%
Idaho	-4.54%
Minnesota	-1.19%
North Dakota	2.73%
Oregon	0.19%
Vermont	1.45%
Wisconsin	-2.68%
Guam	0.11%

As shown in Table 1, the net effect of a 5.06 percent payment reduction with all of the other provisions of the rule is that providers from North Dakota, Oregon, and Vermont on average would experience an estimated increase in payments in CY 2012 of 2.73 percent, 0.19 percent and 1.45 percent respectively, instead of the national average, a 3.52 percent reduction in payments. Furthermore, the net effect of a 5.06 percent payment reduction with all of the other provisions of the rule is that providers from Guam on average would experience an estimated increase in payments in CY 2012 of 0.11 percent.

In addition, the net effect of a 5.06 percent payment reduction with all of the other provisions of the rule is that Alaska providers and Wisconsin providers in the aggregate would experience an estimated reduction in payments in CY 2012 of 0.81 percent and 2.68 percent respectively, instead of the national average, a 3.52 percent reduction in payments.

Table 1 shows that if we were to finalize a 5.06 percent payment reduction, Idaho would experience an estimated 4.54 percent reduction in payments in CY 2012, instead of the national average, a 3.52 percent reduction in payments. However, the non-profit providers and the rural providers in Idaho would experience an estimated reduction in payments in CY 2012 of 1.37 percent and 2.06 percent respectively. Regarding the commenters who expressed concern that a provider association reported that close to half of Minnesota providers would experience negative margins as a result of the proposed payment reductions, we disagree with the provider association's conclusion. The net effect of a 5.06 percent payment reduction with all of the other provisions in the rule is that Minnesota providers, on average, would experience an estimated 1.19 percent reduction in payments in CY 2012, instead of the national average, a 3.52 percent reduction in payments.

Furthermore, preliminary 2009 CR analysis along with MedPAC's projected margin analysis for 2011 suggest that providers in these States have margins which are strong enough to absorb the proposed 5.06 percent payment reduction.

As stated above, we have concerns and questions about the commenter's analyses. Specifically, we believe the commenter may have not taken into consideration all of the provisions of this rule and also may have included in the analyses potential future reductions to HH PPS payments into the 2012 margin forecast (which are not applicable to 2012), and therefore, overestimated the negative impact on providers. We would like to note that industry margins have remained in the mid-double digits in recent years, even in those years in which we implemented similar net payment reductions. We also note that in this final rule, as we describe in detail in the following response to a comment, we are implementing the payment reduction over 2 years, rather than the 1 year we originally proposed. We refer the commenters to Section IV for the impacts of the policies we are finalizing in this rule.

In addition, regarding the commenter's suggestion that we provide State-level impacts which reflect the provisions of the rule, we again refer the commenter to Section IV of this final rule where we describe our State-level analysis for the policies we are finalizing in this final rule. As we described in section IV, we believe that State-level impacts would be misleading unless we also provided breakouts of rural-verses-urban and ownership status of providers within the State.

Comment: Commenters described the burden which they have experienced as a result of recent regulatory and legislative changes. Specifically, commenters described the financial burdens surrounding the Affordable Care Act face-to-face encounter mandate imposed on HHAs and physicians. The commenters stated that HHAs and physicians have needed to hire additional staff to track the face-to-face paperwork. Additionally, commenters noted that the staff time spent tracking, sending, and routing the required documentation, as well as tracking appointments has also been costly for HHAs to absorb. In addition, commenters described administrative burdens associated with the CY 2011 therapy provision which requires a qualified therapist, instead of a therapy assistant, to perform the needed therapy service, as well as assess, measure, and document the effectiveness of the therapy, at key points during a course of therapy treatment. Another commenter stated that payment cuts detract from agencies' ability to attract competent staff. Other commenters stated that CMS should limit any single-year rate reductions to no greater than a combined 2.5 percent. Some commenters suggested CMS phase-in the proposed 5.06 percent adjustment over a 2- to 3-year period. Commenters stated that a 5.06 percent rate reduction is the largest ever imposed in a single year by CMS and stated that the pay cut would have a significant impact as earlier payment cuts have decreased provider margins. Another commenter was concerned that the home health community would not be able to absorb the cumulative effect of recent legislative and regulatory reductions.

Response: Our simulation analysis described in Section II.B, which takes into account all of the proposed policies for 2012 (such as a 5.06 percent payment reduction and the revision of the case-mix weights), projects that payment will exceed costs for all episodes, except for episodes with 20+ therapy visits, of which more than 60 percent would have payment that exceeds their costs. We reiterate that about 6 percent of episodes nationally in 2009 had 20 or more therapy visits. Therefore, we believe that the payment cuts will not detract from agencies' ability to attract staff. We also believe the payments in excess of estimated costs will allow agencies to adapt to recent legislative and regulatory requirements. However, we are sensitive to the challenges HHAs may have had in adapting to the Affordable Care Act provisions which were implemented in CY 2011, such as the face-to-face encounter provision. We also agree that the Affordable Care Act provisions and the CY 2011 therapy changes described by commenters likely required HHAs to incorporate process changes to adhere to these new requirements. As such, we are finalizing a phased-in implementation of a 5.06 percent reduction over 2 years, as some commenters suggested. We believe that by phasing-in the reductions over CY 2012 and CY 2013, we allow HHAs an opportunity to adopt process efficiencies associated with the CY 2011 mandates prior to imposing the full 5.06 percent payment reduction.

In CY 2011 rulemaking, we proposed to apply a 3.79 percent reduction to payments in CY 2011 and an additional 3.79 percent reduction in CY 2012 to account for nominal case-mix growth we identified through CY 2008. However, we deferred finalizing the CY 2012 reduction pending an independent review of our method for identifying real case-mix growth. (That independent review has been completed, as we reported in the CY 2012 HH PPS proposed rule.) Because we believe that providers likely expected and planned for us to impose a 3.79 percent payment reduction in CY 2012, we are finalizing a 3.79 percent reduction in CY 2012 and a 1.32 percent reduction for CY 2013. These reductions enable us to account for the nominal case-mix which we have identified through CY 2009, to follow through with the planned 3.79 percent reduction for CY2012, and to allow for HHAs' adopting process efficiencies during CY 2012.

Comment: Commenters stated that HHAs should be allowed to test the impact of the rate changes using 2011 data.

Response: Given the fact that we currently are in CY 2011, there is not a full year of data from 2011 and we caution HHAs when using a partial year's data in their analysis. In addition, due to the lag in receiving claims, we did not have full data from 2010 when developing the impacts for the CY 2011 HH PPS proposed rule. Therefore, the data used to develop the impacts of our proposed policies are from 2009. We plan to continue to assess the impacts of our policies once new complete data are available. HHAs are welcome to test the impacts of the rate changes on their data; however, when predicting the impacts, it should be noted that all of the policies in the rule should be taken into account (such as the wage index, rural add-on, and the revision of the case-mix weights, and the payment reduction).

Comment: Commenters stated that the rate reductions may adversely affect hospital-based HHAs. They stated that hospital-based HHAs represent 80.9 percent of all providers nationwide with margins below zero and that the Medicare margins which MedPAC presents, only represents freestanding agencies and that hospital-based agencies have lower, negative margins. Commenters stated that hospital-based home care agencies are currently underpaid.

Response: Medicare CR data for hospital-based HHAs does indicate that Medicare margins are lower than those of freestanding HHAs. However, hospital-based HHAs do not account for most of home health care, and there are data issues hindering understanding of hospital-based HHAs' financial status. As stated in their March 2011 Report to Congress, MedPAC focuses on freestanding agencies because they are the majority of providers and because their costs do not reflect the sort of allocation of overhead costs seen in facility-based providers' Medicare CRs (MCR), such as hospital-based HHA MCRs. They explain that in the case of hospitals, which often provide services that are paid for by multiple Medicare payment systems, measures of payments and costs for an individual sector could become distorted because of the allocation of overhead costs or complementarities of services. Another consideration is that Medicare's payment policies should cover the costs of efficient providers. Therefore, given that the payment system is prospective and not based on a provider's reasonable costs, we have reason to question whether the problem, as stated by the commenter, is that hospital-based agencies are underpaid.

Comment: Commenters stated that for those providers who do survive, the cuts will hinder their ability to enhance technology and move to electronic health records.

Response: A reduction in margins as a result of our payment changes may have an effect on the availability of resources for various types of investments. However, our analysis indicates that payments will be more than adequate under our payment changes and would still allow for investments. We do not have sufficient data to evaluate the effect on technology-specific investments from the unusually large margins that have been in existence under the HH PPS, but we welcome information about whether the numerous agencies that operated with high margins under the HH PPS made investments during those years, and the nature of those investments.

Comment: Other commenters stated that CMS should suspend further nominal case-mix adjustments until the rebasing of the HH PPS system required by the Affordable Care Act. A commenter stated that CMS should study the factors driving case-mix growth and analyze the differences in growth by provider characteristics.

Response: We are finalizing payment reductions intended to account for overpayments that were made because of nominal case-mix growth. Since our analysis indicates that margins will remain adequate, and since our analysis of rebasing is still in process, we see no reason to defer nominal case-mix adjustments in this rule. We agree that more data could be useful in understanding case-mix change, and we will continue to solicit suggestions for reliable data that can be incorporated in our studies.

Comment: Commenters urged CMS to commission studies to more accurately estimate real and nominal case weight changes and to help refine the case-mix to more closely align reimbursement with costs and eliminate incentives. Commenters stated that CMS should work on implementing a proper case-mix adjuster which accurately pays for all home health services before implementing a payment reduction.

Response: The home health study under section 3131(d) of the Affordable Care Act allows CMS to not only look at access for vulnerable populations, but also look at other issues with the payment system and payment vulnerabilities. In this study, we plan to examine issues surrounding nominal case-mix growth and ways to better align payment with patient needs. The Report to Congress describing the findings of our study is projected to be available March 1, 2014. In the meantime, while examining ways to better improve the case-mix system, we believe that we need to address previous nominal case-mix growth, and therefore, we plan to implement payment reductions.

Comment: A commenter recommended that CMS seek payment system reforms that are value-based rather than implementing payment reductions. The commenter noted that CMS should factor in the quality of care before implementing payment reductions.

Response: Medicare's value-based purchasing initiatives in home health will build upon current efforts in this area, including Outcome-Based Quality Improvement and CAHPS, and the Value-based Purchasing demonstration. As we develop and refine measures, and incorporate them in payment policies, we will involve stakeholders. Further developing value-based purchasing will take time, but commenters should be assured that it is an important goal for Medicare. However, we cannot ignore nominal case-mix growth in the interim and we believe we need to account for nominal case-mix growth through 2009.

Comment: A commenter stated that the proposed payment cuts along with the proposed case-mix weight changes will hinder agencies ability to calculate their payment.

Response: We note that we are not making significant, structural changes to our case-mix system. We are only revising the case-mix weights. Also, we plan to implement a payment reduction similar to previous payment reductions and have described the base rate payment in the Regulatory Impact Analysis in Section IV of this final rule. Therefore, we do not believe that the proposed policies will hinder agencies' ability to calculate their payment.

Comment: Commenters stated that all of the payment adjustments are based on a false assumption that clinicians and agencies have 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 or clinicians in general gamed the system. However, since our goal is to pay increased costs associated with real changes in patient severity, and nominal coding change does not demonstrate that underlying changes in patient severity occurred, we believe it is necessary to exclude nominal case-mix effects that cannot be shown to be related to changes in patient severity.

Comment: Commenters stated that CMS penalizes providers for improved accuracy in patient assessment and coding. The commenters contributed the increase in case-mix to increased accuracy of OASIS answers and increased coding accuracy as a result of training of their staff and/or the use of certified and trained coders.

Response: Comments referencing coding improvements, such as increasing accuracy, do not recognize that such improvements are an inappropriate basis for increased payment. We believe that measurable changes in patient severity and patient need are appropriate bases 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 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 and be consistent with coding guidelines.

Comment: Commenters stated that CMS should look into alternative ways to account for nominal case-mix changes. Commenters stated that coordinated educations efforts can help control nominal case-mix growth.

Response: Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions for nominal case-mix growth by applying reductions to the base payment. The section does not allow CMS the authority to account for nominal growth in ways other than through payment reductions. We continue to explore ways to prevent future nominal case-mix growth and we welcome any suggestions.

Comment: A commenter stated that the CMS methodology does not recognize home health care's increasing ability to care for more serious medical conditions in the home and ignores changes in patient severity. We received a number of comments stating that home health patients now have more complex conditions than previous populations of home health 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 (IRFs) due to the CMS 60 percent rule. In addition, the commenters cited that there has been a nationwide rebalancing of care in favor of community care settings leading to a higher severity in home care admissions.

Response: Data we presented in the CY 2011 HH PPS final rule (75 FR 70379) indicate that hospital lengths of stay have been declining slightly and lengths of stay in residential post-acute settings before home health admission have increased between 2001 and 2008. We note that the proportion of initial non-LUPA home health episodes preceded by acute care within the previous 60 days has declined between 2001 and 2008, from 70.0 percent to 62.7 percent. This indicates more patients are being admitted to HHAs from non-institutional settings (for example, from the community). Also, post-acute institutional utilization data perhaps consistent with the comment regarding diversion of patients to the home care setting suggest a decline in IRFs as a source of home health 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 home health admission declined by more than a percentage point in 2005 and declined another 1.6 percentage points by 2009, while the percentage preceded by a SNF stay increased half a percentage point in 2005 and has remained above the 2005 level through 2009, the latest year of complete data available (based on a 10 percent beneficiary sample of initial, non-LUPA episodes). We also note that in CY 2005, when CMS began enforcing the IRF 60 percent rule, we initially saw an increase in knee joint replacement patients admitted to home health following hospital discharge. The 60 percent rule (previously, the 75 percent rule), is a criterion used to define IRFs for them to receive payment as an IRF. The rule requires that in at least 60 percent of cases an IRF admits must have one or more selected conditions which have been established as requiring the intensity of care provided in an IRF. However, more current data (2007 and 2009) shows that the prevalence of knee joint replacement patients in home health has dropped from the 2005 levels, though the prevalence is slightly higher than in 2000. The prevalence of hip joint replacement patients has dropped since 2000, as have hip and femur fracture patients. Furthermore, we note that acute stays, which normally precede stays in institutional post-acute care settings, are decreasing in the stay histories of home health patients. Therefore, we question whether there is any evidence showing an increase in home health patient severity as a result of more patients coming to home health as a result of diversion from IRF care.

Comment: Commenters stated that patient care capabilities are changing in home health services and diagnostic-specific care protocols allow targeting of patient populations. Commenters cited utilization of interdisciplinary care providers to improve patient outcomes and to provide best practice interventions, such as the prevention of falls. The commenters further expanded on this idea by stating that there is a movement towards a multidisciplinary approach to care and utilization of broader ranges of therapy services to improve outcomes and that evidence based best practices have improved patient outcome scores.

Response: To the extent that home care agency capabilities are improving, we support such developments and we hope to see them continue. This is an entirely different issue from whether the patient population has changed to the degree as indicated by the nominal coding change we isolate in our analysis.

Comment: Commenters suggested that CMS recognize changes in patient severity, improved patient assessment,

coding and reimbursement changes in their case-mix methodology and work with National Association for Home Care and Hospice (NAHC) to uncover the reasons for case-mix weight changes and to develop a valid methodology for payment reform. Another commenter stated that CMS should include industry stakeholders in the analysis and development of policies, such as the case-mix adjustment cut, that have a significant impact on access to home care services.

Response: Through the public comment process, we have obtained industry views as to the reasons for coding changes. As we have pointed out before, reasons offered, such as improved coding, are not a sufficient basis for raising payment rates. To the extent case-mix change is due to better methods of assessing patients in the home health setting, this does not justify making reimbursements as though the patients really were different in their case-mix levels of severity. We plan to solicit feasible alternative suggestions for scientific approaches to measuring real vs. nominal case-mix change in the home health study under section 3131(d) of the Affordable Care Act.

Comment: Some commenters stated that payment rate reductions due to case-mix weight changes are not warranted because Medicare expenditures on home health 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 that while therapy services for home health 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 home health will lead to more institutional care, for example, by leading to increases in hospital readmissions of post-acute patients.

Response: We have no statutory authority to consider the relationship of CBO projections to home health 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. As stated earlier, we do not believe that the reductions will impede access to care, but we will continue to monitor for unintended consequences. There is no evidence that improvement in home health 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 may explore this area of research in the home health study under section 3131(d) Affordable Care Act.

Comment: Commenters stated that CMS should not implement payment reductions to address high therapy utilization but rather address it by implementing changes to case-mix weights, such as the proposed changes, instead.

Response: We note that we proposed to implement a 5.06 percent payment reduction to account for the residual nominal case-mix growth from 2000 to 2009. The changes to the case-mix weights were proposed to better align payment with costs and to deter incentives which contribute to nominal case-mix growth. Therefore, we believe we still need to implement payment reductions to account for nominal case-mix change from the inception of the HH PPS through 2009.

Comment: 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. Another 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: 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. 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 2010, 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. Such prescribing behavior adds to doubts that services are always provided appropriately. 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) in 2008 may be evidence that increased costs are more than offset by the increased payment associated with therapy. Furthermore, a Senate Finance Committee report concludes that among the major for-profit providers, more therapy was often provided than clinically needed in order to maximize Medicare reimbursement (Senate Finance Committee Staff, ''Staff Report on Home Health and the Medicare Therapy Threshold'', U.S. Government Printing Office, Washington: September 2011). To the extent that unnecessary therapy was provided and contributed to nominal case-mix growth, these are overpayments, regardless of whether the unnecessary therapy had a cost to the HHA that provided it.

In addition, analysis of profit margins indicates that they remain high among HHAs. For example, according to MedPAC's analysis, Medicare margins were 17.7 percent in 2009. This situation suggests that higher payments are not necessarily being offset by increased costs. In March 2011, MedPAC estimated that Medicare margins will be 14.5 percent in 2011, taking into account the then-expected payment reductions (MedPAC, *Report to Congress: Medicare Payment Policy,* March 2010). Our estimates suggest aggregate Medicare profit margins in home health will remain strong under the payment policies we are finalizing with this rule.

Comment: Commenters stated that there is an increased volume of episodes that have therapy utilization and that there have been improved patient

outcomes. Some of these commenters cited Table 8–5 in the March 2011 MedPAC Report to Congress. They stated that the beneficiary outcomes have greatly improved in all functional measures with the increased therapy services.

Response: There is not yet a body of rigorous literature that provides evidence tying improvements in home health outcome measures to the increased volume of therapy provided under the HH PPS. The standard for such evidence would be stronger than a broad correlation between improvement rates in outcomes and amount of therapy provided. In addition, we disagree that the March 2011 MedPAC Report to Congress implied or concluded that increased therapy utilization has improved patient outcomes. Rather, in the March 2011 Report, the Commission criticized the home health measures for not capturing changes in quality that were related to the patient's need for home health care. The Report further described that the improvement in walking measure is reported for all patients regardless of whether they needed home health to address a mobility condition.

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 which 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. For example, the models do incorporate information about change in the types of patients more likely to use therapy, such as post-acute joint replacement patients. CMS has access to the claims histories and other administrative data for patients in our samples, and we welcome suggestions about how to better use these resources in finding alternative variables more indicative of the need for therapy, particularly if the suggestions involve the use of data and variables that are not HHA-determined.

Comment: A commenter stated 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.

Response: We disagree with this comment. The predictive model for real case-mix was designed in 2007 and includes a comprehensive set of variables. We augmented the set of predictor variables this year by adding HCC data. 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: The commenter stated that MedPAC is researching and developing revised payment models which could bring therapy reimbursement more in line with how other home health services are paid for and any dramatic reimbursement changes to the HH PPS should be postponed in anticipation of a more complete revision to the payment methodology.

Response: We do not believe our proposals represent dramatic reimbursement changes. We have strived to maintain the look and feel of the refined system of 2008 in our proposals this year. We agree that dramatic changes to the HH PPS system should await the congressionally mandated study currently underway, pursuant to Section 3131(d) of the Affordable Care Act. This study may be followed by a demonstration to test major revisions to the payment methodology.

Comment: A commenter implied that the industry did not play a role in developing the HH PPS and implied that when OASIS was first used, there was a significant variation in the reporting and that the industry was disadvantaged.

Response: We followed the Administrative Procedures Act (APA) in implementing the HH PPS under the mandate in the Balanced Budget Act of 1997. Under the APA, we solicited public comments in 1999 on the then-proposed system. OASIS itself was developed with industry participation for the purpose of measuring home health outcomes (see GAO–01–205, January 2001, Appendix II). A version of OASIS was used in the original case-mix research that led to the design of the HH PPS case-mix system. The research results indicated that adequate case-mix adjustment of payments could be achieved using OASIS variables. We have noted in previous regulations that the average case-mix weight nationally, as estimated from OASIS assessments in the 12 months leading up to October 1, 2000, was about 13 percent higher than the average in the sample of agencies whose data were used for the case-mix research. We used the estimate from the 12 months leading up to October 1, 2000 as our baseline for measuring case-mix change because it represented a very large, broad-based set of episodes. It did not reflect the earliest days of OASIS use. Given that coding practices continually evolved subsequent to the last 12 months ending October 1, 2000, and that agencies were not subject to the HH PPS incentives during the 12 months ending October 1, 2000, we believe the baseline period that we selected is the most appropriate one to use to begin measuring coding change that occurred in relation to the introduction of the HH PPS. Any other period subsequent to our baseline builds in impacts on coding of the HH PPS and is questionable to use from the point of view of responsible fiscal stewardship.

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 home health 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. Other 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: We disagree. The prediction model for real case-mix is an empirical model, the findings of which are based entirely on empirical evidence. We also disagree with the commenter's suggestion that we have not validated the data or methods used to calculate the payment reduction. Over the last several years, we have continued to evaluate our data and methods, and this year, we procured a review of our model by Dr. Grabowski and his team at Harvard University, who found our model robust.

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. This year, additional diagnosis data, based on physician and hospital diagnoses in the patient's claims history, were added in the form of HCC indicators. Measurable changes in patient severity and patient need, factors mentioned by commenters, are an appropriate basis for changes in payment. Our model of real case-mix change has attempted to capture such increases.

We recognize that models are potentially limited in their ability to pick up more subtle changes in a patient population such as those alluded to by various commenters. Yet in previous regulations we presented additional types of data suggestive of only minor changes in the population admitted to home health, and very large changes in case-mix indices over a short period. We included among these pieces of evidence information about the declining proportion of home health episodes associated with a recent acute stay for hip fracture, congestive heart failure, stroke, and hip replacement, which are four situations often associated with high severity and high resource intensity. 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 CY 2011 HH PPS 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 so as to cause an increase of 0.0533 in the average case-mix weight in a single year. Furthermore, we concluded that the large change was not due to our use of the new, 153-group case-mix algorithm in 2008, because when we applied the previous case-mix system and the new system to a sample of 2007 claims, the average weight differed very little (the difference was 0.0054). That is, the algorithms in the previous and new case-mix systems provided highly similar case-mix weights on the sample of 2007 claims. We further examined the diagnosis coding on OASIS assessments linked to the 20 percent claims sample and found a large increase between 2007 and 2008 in the reporting of secondary diagnosis codes (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.

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 home health care, not just those discharged directly from hospitals.

Response: Many variables in our model are applicable to patients who have not used hospitals recently, including variables relating to demographic status and post-acute care utilization. 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. Finally, this year we also added a new source of information to the model, physician diagnoses from the claims history of each patient and hospital diagnosis information from all hospitalizations occurring in the year of the HH PPS episode of the patient. This represented a substantial increase in the amount of information available about patient health characteristics. We believe that, especially since we made this change, the model includes a rich set of patient measures. 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: 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. Commenters stated that the signs for various variables in the model are counterintuitive. 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; 72 FR 49762, 49780, 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. Furthermore, we believe that often the signs that commenters find counterintuitive are not so upon careful consideration of the variables already controlled for in the model.

Comment: Some of the technical concerns are that the model contains numerous variables that are not statistically significant and may provide spurious results.

Response: To avoid omitted variable bias, we believe it is prudent to include all available variables for which there is good reason to believe that they may be causally related to patient case-mix, and therefore, the models contained some statistically non-significant variables. In addition, the non-significant variables do not appreciably alter the results of the case-mix measurement 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 (prior to the recent addition of HCC variables), 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 they would like the model to meet a minimum requirement for a level of accuracy and reliability that is at least equivalent to the case-mix adjustment model that it is assessing. The commenters stated that the current HH PPS case-mix model had an R-squared explanatory power of over 40 percent while the case-mix weight change assessment model has an R-squared around 10 percent. The commenter states that the regression model R-square dropped from 19 percent to 10 percent in the 2008 analysis and the decrease in the R-square is ''unclear and unexplored.'' They stated that since the R-square of the 80 HHRG case-mix model was 0.21 while the R-square of the 153 model was 0.44, the R-square value for the case-mix measurement model should be higher for the model using the 153 grouper.

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. The commenter stated the 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. We note that the commenter's comments correspond to the older case-mix prediction model (which assessed real case-mix growth from 2000–2007 and from 2007–2008). We have since updated our case-mix prediction model to include HCC data and our case-mix model assesses real case-mix growth from 2000–2005, 2005–2007 and from 2007–2009.

We also note that we disagree that the difference in R-squares for the models indicates that the prediction model for real case-mix is unreliable. Comparing the results for the 2000–2005 and 2005–2007 periods, four of the top five drivers of predicted case-mix change are the same in both models, as are 13 of the top 20. Similarly, 13 of the top 20 drivers are the same for results from 2005–2007 and 2007–2009, including the HCC community score. 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 in the 2000–2005 analyses (which account for almost 80 percent of the total predicted change in that time period), 48 have the same sign in the 2007 model and 30 also have the same sign for the 2009 model.

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, pertaining to the 2000–2005 and 2005–2007 periods, and the 153 case-mix weights for the second model, pertaining to the 2007–2009 period). 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.

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, in last year's analysis, we rebased the prediction model to the 2008 data, the first year that the 153-group model was used for paying home health providers, creating a 2007–2008 segment. We combined the results from the original IPS-period equation with the results from the rebased 2008 equation for last year's analysis. For this year's analysis, again we defined segments to accommodate data availability. We defined three segments. We broke the 2000–2007 period that we previously analyzed into two periods, 2000–2005 and 2005–2007, because we added several variables derived from HCC model to the 80 HHRG model. It was not possible to include HCC variables in analyses of years prior to 2005. The third segment covered 2007–2009 instead of 2007–2008, to update the data to the most

current year available. This year's analysis used 2009 data, rather than 2008 data, for rebasing to the 153-group model.

Comment: Commenters criticized the model's reliance on hospital DRG data stating that over half of all Medicare home health patients are admitted to care from a setting other than a hospital and many of the patients receive care far extended past an initial episode. Commenters stated that the APR–DRG variables are less relevant for multiple episode patients. Another concern was that 848 of the 902 variables are APR–DRG related to prior use hospitalization.

Response: We disagree that the utility of the hospital information in the case-mix change analysis is so limited, and with the addition of HCC data, we have enhanced the robustness of the variable set used for the analysis to include physician diagnoses and diagnoses of other clinicians, as well as Medicaid eligibility. Regardless of whether the patient came directly from a non-hospital-setting (for example, home or a post-acute institutional stay), information from a hospital stay preceding home health 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 home health episode. A recent hospitalization, whether or not there is an intervening period spent in some other setting before home health admission, is common before admission to home health. 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, 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 stated that the model should recognize that home health patients are often treated in the home for conditions other than the primary condition that led to hospitalization and should consider that patients may have multiple episodes of care such that a prior hospitalization may be of little relevance to the condition of the patient.

Response: We believe our addition of HCC data addresses this comment. The data reflect the cumulative diagnostic information from the patient's claim history in the year of the episode. We would like to remind commenters that the real case-mix prediction model is not limited to diagnoses. The model also takes into account demographic factors, as well as utilization indicators of health status, such as Part A utilization measures. Moreover, the model measures the relationship between these factors and case-mix.

Comment: A commenter stated hospital discharge data demonstrate that home health 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 HHAs. As one of the measures for patient severity is prior hospitalization, it is believed to be unaffected by the home health CMI. The CMI for the prior hospitalization can be assumed to be a proxy measure of the ''real'' case-mix index (CMI). 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 1.630 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 CMI 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: The commenters stated that the Harvard team validation analysis confirms that patients discharged from a hospital to home health services are significantly different in terms of case-mix weight changes than those admitted to home health without a prior hospitalization. The case-mix weight change increased by 21.16 percent for those who were discharged to home health while the case-mix weight change increased by only 15.85 percent for those who were discharged to home health without a prior hospitalization.

Response: Both of those case-mix weight change values are substantial. In addition, as described in the CY 2012 HH PPS proposed rule, the results of the MEPS analysis did not provide evidence to suggest that the Medicare home health population has experienced a decrease in their health status over time. Given these results along with the finding of significant nominal case-mix percentage increases for the post-acute and community patients, the Harvard team concluded that the current model adequately measures real case-mix growth for home health patients, including patients admitted to home health from the community. Furthermore, we note our real and nominal case-mix change estimated for purposes of arriving at the case-mix change adjustment to the rates combine data from both populations.

Comment: Many commenters suggested that all of the payment adjustments are based on a flawed foundation and suggested that CMS should not use data from IPS and early PPS years to compare increased case-mix weights. Commenters recommend analyzing data with a different base year and analyzing case-mix weight changes for 2008 to current to see how much increase occurred in more recent years.

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

We believe the declining prevalence of recent acute discharges is due in part to more patients incurring recertifications after admission to home health care, and also due to more patients entering care from the community. The shortening lengths of stay at the right tail (high percentiles) of the distribution may reflect changing utilization of long-term-care hospitals during recent years. The conclusion we draw from these data is that while patients on average have shorter hospital stays, agencies are also facing a smaller proportion of home health episodes in which the patient has been acutely ill in the very recent past. Also, the detailed data on the distribution of stay lengths suggest that for the most part lengths of stay for such patients remained fairly stable through 2009.

TABLE 2: Percentiles of acute hospital length of stay (days) (2006-2009)

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

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

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

the very last stay before the claim from-date, increased from 12.7 to 14.3 days. Our interpretation of these statistics is that patient acuity has been increasingly mitigated by longer post-acute stays for the substantial number of home health patients that use residential post-acute care prior to the start of a home health episode. Patient acuity also was mitigated by growing numbers of home health recertifications.

Comment: Commenters stated that CMS uses inconsistent approaches in estimating the coding adjustment among provider sectors. They cited that over the last four years, CMS has used different case-mix change assessment models for post-acute providers: IRFs, LTCHs, and HHAs. Other commenters stated that the methodology ''used to establish the reduction percentage'' in the inpatient system was flawed and were concerned that the methodology used to establish the payment reduction for home health is flawed as well.

Response: The payment systems, institutional conditions, data resources, case-mix assignment procedures, and many other aspects differ across care settings. Therefore, individual case-mix assessment methodologies must be developed for each of the post acute care sectors. Our general approach is consistent with the original approach CMS used to analyze the coding change problem affecting IRFs. Also, in terms of evaluating case-mix methodologies in the different settings, the 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: Commenters stated that there should be no application of the adjustment to medical supplies unless CMS can establish that there is a change in case-mix weights specifically regarding medical supplies that is not due to real changes in patient characteristics and the proposed rule is unclear whether the adjustment factor will apply to NRS.

Response: The 3.79 percent payment reduction in CY 2012 and the 1.32 percent payment reduction in CY 2013 that we are finalizing in this final rule will not be applied to non-routine medical supplies. The payment reductions will only be applied to the national standardized 60-day episode rates to fully account for growth in nominal case-mix from the inception of HH PPS through 2009. We will further explore potential payment reductions to non-routine medical supplies for future rulemaking.

Comment: One commenter stated how there is much uncertainty surrounding how the ''super committee,'' created as part of the recent debt limit deal, will move forward assigning cuts in Federal spending over the next ten years and if the committee and/or the Congress fail to reach a compromise, there may be cuts to Medicare home health rates in conjunction with the regulatory cuts that CMS is proposing. (0038) The commenter was concerned with the combined effect of these additional cuts along with our payment reduction.

Response: We will continue to monitor HHA margins and effects of payment policies on patients' access to care. CMS also must comply with current and any future Medicare laws passed by the Congress. In addition, we cannot comment on any potential legislation which the Congress may be considering.

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 home health 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 suggested that CMS use this more transparent process which would still enable rate adjustments to be implemented provided that there is reliable evidence that there are higher case-mix scores resulting from factors other than changes in patient condition.

Response: We commissioned a review of the case-mix change methodology, as we described in our proposed rule and elsewhere in this final rule. The research team of highly qualified personnel determined that an examination of the consistency of the results across types of episodes and providers, which they conducted themselves, would provide information about the reliability of the method. They considered information that they developed from the MEPS survey as well. We have not commissioned work based on a medical records sample. We note that a medical records sample could be used to determine payment reductions; however, there are many difficulties and limitations to this analysis. First, to produce reliable results, we would need to collect a large sample which would require significant financial resources that may not be available. We would a need a sizable sample of records from both the IPS period and from a follow-up year (for example, 2009). In addition, based on our past experience in retrieving old records, it is difficult to find enough records to constitute a valid broad-based sample. 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: Commenters criticized the evaluation by the Harvard team. They stated that the Harvard team did not attempt to determine if the results were accurate and only validated the idea that a method that does not rely on home health specific patient data results in similar conclusions when reviewed in comparison to alternative methods that do not consider home health patient characteristics.

Response: The Harvard team was asked to review the appropriateness and strength of evidence from the case-mix change methodology we used. After their examination, they concluded that the methodology was robust and valid.

Comment: One commenter stated that they reviewed the report by Dr. Grabowski and his team at Harvard and found it provided compelling support for the case-mix measurement methodology used in the proposed rule.

Response: We thank the commenter for the comments and the support.

Comment: Commenters disagreed with the use of HCC data. The commenters stated that the HCC information has no bearing on the home health-specific condition of patients nor the condition at any provider setting and that an individual may need different levels of care at any given point in time. The commenters stated that the reliance on HCC does not offer the granular-level review of patient characteristics that is needed. Another

commenter stated that the methodology used to risk adjust for managed care is not the same as risk adjusting for home health patients at the time they received services and that they thought that this difference was not taken into account in the case-mix measurement model.

Response: We added the HCC data partly as a response to commenters' criticisms that the model of real case-mix change was too reliant on hospital-generated claims information. We disagree with the statement that the HCC information has no bearing on the home health-specific condition of patients, because we used the HCC information for the year in which the episode took place. The patient's conditions during that year, as reflected in all the diagnoses associated with physician visits, certain other types of clinician encounters, and hospital stays occurring that year, in addition to information such as Medicaid enrollment included in the HCC data, provide a relatively comprehensive picture from administrative data of the patient's health status. We do not find that a granular level review of patient characteristics would be feasible, given the immense resources needed for a large set of independent reviews.

Comment: Commenters were concerned with CMS' use of 2009 data, stating that home health services have changed from 2009 to today.

Response: As in previous rulemaking since the start of the HH PPS, we continue to use data samples that represent a 2-year lag of the service date relative to the year in which we conduct the analysis. The 2009 claims data matched to OASIS assessments and Part A information, as well as HCC information, are a complex set of analytic files that should be based on a complete year of data, to assure representativeness. If we were to begin file construction before having all the claims, we would introduce error into the results (in general, more complicated claims take longer to prepare and submit). Furthermore, we did not make major changes to the payment system that would affect most agencies between 2009 and 2011, and so we do not have strong reasons to believe that services patterns have changed dramatically. We noted in our proposed rule that in 2009 the major outlines of the therapy episode distribution exhibited a continuation of the outline established in 2008, the first year under the refinements.

An alternative to using 2009 data to determine nominal case-mix growth would be to project the level of nominal case-mix growth for 2010 and beyond and make payment reductions based on our projections. However, these projections may result in payment reductions that are larger than those being implemented. We may consider such a methodology change in future rulemaking.

Comment: The commenters stated that the payment reductions fail to take into account home health coding policy changes that negate the risk of coding weight increases, such as the elimination of hypertension from the case-mix system and the re-weighting of therapy episodes. Commenters suggested that CMS consider the impact of the hypertension adjustment in the overall analysis of nominal case-mix growth. Other commenters requested that CMS not make drastic changes to the case-mix while implementing the proposed rate reductions.

Response: We note that when removing the two hypertension codes, we reallocated the resources and revised the weights in a budget neutral manner so that they would result in the same approximate aggregate expenditures as 2009. Therefore, when removing the two hypertension codes, we are not taking away money from the case-mix system, and therefore, we can fully account for case-mix growth from 2000 to 2009.

We also note that the payment reductions we have proposed are to compensate for nominal coding changes that occurred through 2009 and we proposed to implement the elimination of hypertension beginning in 2012. Based on our analysis discussed in Section II.B, we believe a revision in the case-mix weights is warranted and are therefore proposing the change to the case-mix weights along with the payment reductions.

Comment: Commenters stated that external data references show indications of real changes in patient characteristics. They stated that the Medicare Expenditure Panel Survey (MEPS) Data analysis shows that patients are getting sicker every year and data may show a higher ''real'' case-mix change than CMS estimates.

Response: As stated in the proposed rule, to address the comment that a study which used MEPS data showed a higher rate of real case-mix growth in the entire Medicare population than our model estimated for Medicare home health patients, a more detailed analysis of the MEPS data was performed. The trends in health status of four different populations from 2000 to 2008 were analyzed. The data for the analysis were obtained from the MEPS 2000 and 2008 Full Year Consolidated Data files. The four populations that were analyzed were: (1) The full MEPS sample; (2) all Medicare beneficiaries, defined as all respondents ever having Medicare in a given year; (3) all home health patients, defined as having at least one home health provider day in a given year; and (4) all home health Medicare beneficiaries, defined as all respondents with any Medicare home health charges. Two measures of self-reported health status and one measure derived from patient information that screened for ADL limitations were used to determine the trends in health status. These types of measures have been shown to be highly correlated with actual health (Ware and Sherbourne, 1992; McHorney, Ware, and Raczek, 1993). The three measures which were analyzed for each of the populations were: (1) Whether the respondent indicated perceived health status of ''poor'' or ''fair'' as opposed to those indicating health status as ''good,'' ''very good'' or ''excellent;'' (2) whether the respondent indicated if pain limited normal work (including work in the home) in the past 4 weeks ''extremely'' or ''quite a bit'' as opposed to those indicating pain limited work ''moderately,'' ''a little bit,'' or ''not at all,'' and (3) whether respondents had a positive screen for needing assistance with ADL. In all cases, responses such as ''refused,'' ''don't know,'' or ''not ascertained'' were omitted from the analysis. The Medicare analysis samples consisted of 3,371 and 4,144 beneficiaries in 2000 and 2008, respectively. The Medicare home health subsamples consisted of 174 and 289 beneficiaries in 2000 and 2008, respectively. The survey responses were then weighted using pre-constructed MEPS survey weights to estimate nationally representative changes in the three health status variables.

All three measures indicated a slight increase in the overall health status of the Medicare home health population. Two of these results were not statistically significant, but the percent of home health Medicare beneficiaries experiencing ''extreme'' or ''quite a bit'' of work-limiting pain decreased substantially, from 56.6 percent in 2000 to 45.4 percent in 2008 ($p=0.039$). Unlike Dr. Deb's original study, the new MEPS analysis focuses specifically on Medicare home health users (as opposed to the entire Medicare population), and it is not reliant on expenditure data. A limitation of the Debs case-mix measure, which relies on expenditure data, is that it could reflect large increases in expenditures, such as drug expenditures, but any relationship to actual increases in impairments and other reasons for using home health resources is unclear. A possible

limitation of the new MEPS analysis is that the sample of Medicare home health respondents is relatively small, notwithstanding that the result of one of the three measures was statistically significant. Also, the ADL screening item may not capture a change in the frequency of very severe ADL limitations since the measure may be insensitive to changes at high levels of disability. However, the Harvard team asserted that the methods of the new MEPS analysis are more appropriate for assessing whether there are increases in the severity of illness burden that would specifically indicate a need for more resources in the Medicare home health population. Based on the two kinds of evidence, and a recognition of the limitations of both, we conclude that the MEPS data provide no evidence of an increase in patient severity from 2000 to 2008.

Comment: Commenters stated that the OCS data analysis on OASIS measures regarding a patient's functional status unrelated to HH PPS HHRG calculations showed that there were declines in all nine functional categories and showed increased patient acuity from 2006–2008 as measured by ADL assessments of decreasing functional capabilities of home health patients. They also stated that OCS data analysis on OASIS measures of clinical conditions that are unrelated to HH PPS HHRG calculations shows a ''large increase'' in acuity as measured by changes in clinical conditions and there are increases in the number of patients requiring IV therapy, parenteral nutrition and those who have urinary tract infections at the start of care. They stated that the data also showed an increased inability to manage oral and injectable medications. They stated that the OASIS measures are not likely to be ''upcoded'' to secure higher reimbursement as none of the measures have a direct or indirect impact on payment and that the decreases in ADL incapacities are correlated with increase in use of therapy services. 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.'' Commenters stated that other data showed that home health care patients have increased functional limitations and more complex clinical conditions than in past years.

Response: Contrary to the trends reported by the commenter pertaining to treatments at home, our analysis from 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. The proportion of episodes involving parenteral nutrition remains at 0.2 percent or less during that period. As we have stated in previous regulations, 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: Commenters stated that patients are also taking many more medications.

Response: OASIS-C includes information about medication use, but we do not have broad-based information about changes in numbers of medications in home health users in recent years. While we intend to examine the possible role that new variables in OASIS-C, including medication use, can play in case-mix adjustment, whether a trend indicative of increased medication use is important for measuring real change in case-mix over time depends on the extent to which its effect is independent of other factors recognized in our real case-mix change analytic procedure. Also, the challenge of obtaining historical data is great, but we can at least start tracking medication use with the availability of OASIS-C.

Comment: One commenter was supportive of the payment reduction. The commenter stated that they believed that unwarranted overpayments attributable to coding practices should be recovered when possible and that the reduction is consistent with the experience of other prospective payment systems. The commenter stated that the payment reduction should not create payment adequacy or access to care issues since HHAs are projected to have margins exceeding 14 percent in 2011. The commenter stated that CMS should continue to examine nominal case-mix growth in the future and adjust payments accordingly.

Response: We thank the commenters and will continue to monitor nominal case-mix growth and implement payment adjustments as needed. In summary, we thank the commenters for their thoughtful and comprehensive comments. As we described above in response to comments, we are finalizing a phased-in implementation of a 5.06 percent reduction over 2 years, as some commenters suggested. We believe that by phasing-in the reductions over CY 2012 and CY 2013, we allow HHAs an opportunity to adopt process efficiencies associated with the CY 2011 legislative and regulatory requirements prior to imposing the full 5.06 percent payment reduction.

In CY 2011 rulemaking, we deferred finalizing a proposed 3.79 percent reduction to the CY 2012 national standardized 60-day episode rates to account for nominal case-mix growth we identified through CY 2008 pending an independent review of our method for identifying real case-mix growth. We believe that providers expected and planned for us to impose a 3.79 percent payment reduction in CY 2012. As such, we are finalizing a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013 to the national standardized 60-day episode rates. These reductions enable us to account for the nominal case-mix which we have identified through CY 2009, to follow through with the planned 3.79 percent payment reduction for CY 2012, and to allow for HHAs' adopting process efficiencies during CY 2012.

B. Case-Mix Revision to the Case-Mix Weights

1. Hypertension Diagnosis Coding Under the HH PPS

As stated in the CY 2012 HH PPS proposed rule, in CY 2011 rulemaking, we proposed to remove ICD–9–CM code 401.1, Benign Essential Hypertension, and ICD–9–CM code 401.9, Unspecified Essential Hypertension, from the HH PPS case-mix model's hypertension group. Beginning with the HH PPS refinements in 2008, hypertension was included in the HH PPS system because

the data used in developing the refinements (data from 2003 and 2005) suggested it was associated with elevated resource use. As a result, the diagnoses Unspecified Essential Hypertension and Benign Essential Hypertension were associated with additional points from the four-equation model and, therefore, with potentially higher case-mix weights in the HH PPS case-mix system. When examining the trends in reporting of hypertension codes from 2000 to 2008, our analysis showed a large increase in the reporting of codes 401.1 and 401.9 in 2008. However, when looking at 2008 claims data, the average number of visits for claims with code 401.9 was slightly lower than the average for claims not reporting these hypertension codes. In the CY 2011 HH PPS proposed rule issued on July 23, 2010, we proposed to remove codes 401.1 and 401.9 from our case-mix model based on preliminary analysis of the trends in coding and resource use of patients with these codes. We suspected that the 2008 refinements, which newly awarded points for the diagnosis codes 401.1 and 401.9, led to an increase in reporting of these codes and that this reporting was a key driver of the high 2008 growth in nominal case-mix.

In response to this proposed policy change, we received numerous comments, several of which stated that additional analysis was needed to substantiate the rationale for removing hypertension codes 401.1 and 401.9. In the CY 2011 HH PPS final rule, we withdrew our proposal to eliminate 401.1 and 401.9 from our model and stated our intention to do a more comprehensive analysis of the resource use of patients with these two hypertension codes. As noted in our CY 2012 HH PPS proposed rule, we have since completed a more thorough analysis. Based on the results of our latest analyses, we proposed to remove ICD–9–CM code 401.1, Benign Essential Hypertension, and ICD–9–CM code 401.9, Unspecified Essential Hypertension, from the HH PPS case-mix model's hypertension group. Our data showed there continued to be an increase in the prevalence of ICD–9–CM code 401.9 from 2008 to 2009. In addition, agencies (regardless of ownership type) typically had a twofold or higher increase in the prevalence of a 401.9 diagnosis from 2005 to 2009, with the exception of the East North and the West North Central regions, which had an increase of about 1.7- and 1.5-fold, respectively. Most compelling, our analysis indicates that currently these diagnoses are not predictors of higher home health patient resource costs. Rather, current data indicates a lower cost associated with home health patients when these codes are reported. The results from two regression models testing the impact of the two hypertension codes on resource costs provided strong support for removing the 401.1 and 401.9 diagnoses from the case-mix system. The results showed that the presence of these diagnoses is associated with lower costs, when controlling for other case-mix related factors. Therefore, we proposed to remove codes 401.1 and 401.9 to more accurately align payment with resource use.

In the CY 2011 HH PPS final rule, in response to comments, we stated that if we were to finalize removing these codes from our case-mix system, we would do so in such a way that we would revise our case-mix weights to ensure that the removal of the codes would result in no change in aggregate expenditures. Therefore, we proposed to revise the HH PPS case-mix weights in such a manner so as to not reduce aggregate home health expenditures. Please see the following section for details on our revision to the case-mix weights. The proposed revisions of the case-mix weights redistributed HH PPS payments among the case-mix groups such that removal of these hypertension codes was budget neutral.

2. Revision of the Case-Mix Weights

As we described in section II.B.1 of this preamble, we proposed to revise our HH PPS case-mix weights to remove two hypertension codes from our case-mix system while maintaining budget neutrality. In the CY 2012 HH PPS proposed rule, we also justified another proposal for further revisions to the case-mix weights because of incentives that exist in the HH PPS to provide unnecessary therapy services. We described that our review of HH PPS utilization data shows a shift to an increased share of episodes with very high numbers of therapy visits. This shift was first observed in 2008 and it continued in 2009. In last year's regulation, we described an increase of 25 percent in the share of episodes with 14 or more therapy visits. In the 2009 sample, the share with 14 or more therapy visits continued to increase while the share of episodes with no therapy visits continued to decrease. The frequencies also indicate that the share of episodes with 20 or more therapy visits was 6 percent in 2009 (data not shown), which is a 50 percent increase from the share of episodes of 2007, when episodes with at least 20 therapy visits accounted for only 4 percent of episodes.

Furthermore, we described that in their 2010 and 2011 Reports to Congress, MedPAC suggests that the HH PPS contains incentives which likely result in agencies providing more therapy than is needed. In their March 2010 Report to Congress, MedPAC stated that ''therapy episodes appear to be overpaid relative to others and that the amount of therapy changed significantly in response to the 2008 revisions to the payment system.'' In support of this statement, MedPAC showed that in 2008, there was a sudden shift to episodes with therapy services at the new therapy thresholds, which suggests inappropriate therapy utilization. In their March 2011 Report to Congress, MedPAC stated, ''The volume data for 2009 indicate that the shifts that occurred in 2008 are continuing * * * Episodes with 14 or more therapy visits increased by more than 20 percent, and those with 20 or more therapy visits increased by 30 percent.''

Also, in their March 2011 Report to Congress, MedPAC suggested that the current HH PPS may ''overvalue therapy services and undervalue nontherapy services.'' In this report, MedPAC describes that HHA margins average 17.7 percent in 2009, with 20 percent of agencies achieving an aggregate margin of 37 percent. MedPAC further stated that their analysis of high-margin and low-margin agencies suggests that the HH PPS overpays for episodes with high case-mix values and underpays for episodes with low-case-mix values. Furthermore, MedPAC reported that HHAs with high margins had high case-mix values which were attributable to the agencies providing more therapy episodes (MedPAC, March 2011 Report to Congress). MedPAC went on to assert that ''unless the case-mix system is revised, agencies will continue to have significant incentives to favor therapy patients, avoid high-cost nontherapy patients, and base the number of therapy visits on payment incentives instead of patient characteristics.''

We stated that we concur that the therapy utilization shifts and the correlation between high agency margins and high volumes of therapy episodes strongly suggest that the costs which the HH PPS assigns to therapy services when deriving the relative payment weights are too high in comparison to actual costs incurred by agencies for therapy services. We believe that one factor which contributes to this overpayment for therapy services is the growing use of therapy assistants, instead of qualified

therapists, to provide home health therapy services. Current data suggest that the percentage of therapy assistants that is reflected in the therapy-wage weighted minutes used in the calculations of HH PPS relative resource costs is too low. For our 2008 refinements, to construct the relative resource costs for episodes, we used the labor mix percentages reported in the Occupational Employment Statistics (OES) data by the Bureau of Labor Statistics. In 2005, which is the year of data that was used to develop the HH PPS refinements, the OES data showed that 15 percent of physical therapy was provided by therapy assistants and that 11 percent of occupational therapy was provided by therapy assistants. This data was then used to develop the resource costs for episodes which were used to develop the current HH PPS payment weights. In 2008, the OES data showed that 19 percent of physical therapy was provided by therapy assistants and that 13 percent of occupational therapy was provided by therapy assistants. In addition, by 2009, OES data has shown that the percentage of physical therapy provided by therapy assistants was 20 percent and the percentage of occupational therapy provided by therapy assistants was 16 percent. We noted that these statistics reflect the mix for all home health providers. We also noted that in CY 2011, we began collecting G-code data on HH PPS claims which will enable us to quantify the percentage of therapy assistants who are providing therapy and to assess how the percentages vary relative to the quantity of therapy provided and the type of provider. We have since performed some preliminary analysis on the G-code data, which is further discussed in our responses to comments.

In the CY 2012 HH PPS proposed rule, we stated that we believe that MedPAC has provided strong evidence that our reimbursement for episodes with high therapy is too high. Also, based on MedPAC's analysis and our own findings, we believe that the resource costs reflected in our current case-mix weights for therapy episodes, in particular for those episodes with high amounts of therapy, are higher than current actual resource costs and that an adjustment to the HH PPS therapy case-mix weights is warranted. We noted that fully addressing MedPAC's concerns with the way the HH PPS factors therapy visits into the case-mix system will be a complex process which will require more comprehensive analysis and potentially additional structural changes to the HH PPS. While we plan to address their concerns in a more comprehensive way in future years, for CY 2012 we proposed to revise the current case-mix weights by lowering the relative weights for episodes with high therapy and increasing the weights for episodes with little or no therapy. It should be noted that we proposed to revise the case-mix weights in a budget neutral way. In other words, our proposal redistributed some HH PPS dollars from high therapy payment groups to other HH PPS case-mix groups, such as the groups with little or no therapy. We believe our proposed revision to the payment weights would result in more accurate HH PPS payments for targeted case-mix groups while addressing MedPAC concerns that our reimbursement for therapy episodes is too high and our reimbursement for non-therapy episodes is too low. Also, we believe our proposed revision of the payment weights will discourage the provision of unnecessary therapy services and will slow the growth of nominal case-mix.

Our detailed approach, analysis, and case-mix revision methodology which supported our proposal was described in our CY 2012 HH PPS proposed rule. Before we described our approach to revise the case-mix weights to address therapy incentives, we first explained the changes we made to remove the hypertension diagnoses ICD–9–CM code 401.1, Benign Essential Hypertension, and ICD–9–CM code 401.9, Unspecified Essential Hypertension from our case-mix system. Our method of redistributing the resources started with changes to the four-equation model, which is the foundation for the subsequent revised payment regression and creation of revised case-mix weights. The changes to the four-equation model as described in the proposed rule are reiterated below.

To examine the effects of removing the two hypertension codes 401.1 and 401.9 from the case-mix system and determine whether the thresholds for the clinical severity indicators need to be changed if 401.1 and 401.9 are removed from the case-mix system, we estimated the four-equation model with and without codes 401.1 and 401.9 in the hypertension group. We used 2005 data for this estimation because we wanted to achieve comparability between the current four-equation model with the revised four-equation model without the two hypertension codes using the same sample upon which we based the 2008 case-mix system refinements. We estimated the revised four-equation model to maintain the same variables we developed for our current four-equation model and thereby minimize changes to our current model and scoring system. The adjusted R-squared value for the four-equation model without codes 401.1 and 401.9 derived from 2005 data was 0.4621. We then used the coefficients from the four-equation model without codes 401.1 and 401.9 to determine the points which would be associated with all the clinical and functional severity levels found in our current four-equation model, as described on Table 2a of the CY 2008 HH PPS final rule (Table 3). We note that Table 3 has been updated since the CY 2012 HH PPS proposed rule to reflect OASIS-C items.

When comparing the four-equation model with the two hypertension diagnoses (which is equivalent to our current model) to the four equation model without the two hypertension diagnoses, there were some differences in the points assigned to variables (Table 4). We detailed these differences, which were no larger than one point in the 58 (out of 225) variables affected. Table 3 shows the points for each variable after the re-estimation of the four-equation model.

BILLING CODE 4120–01–P

TABLE 3: Points Associated with the Updated 4-Equation Model without hypertension codes 401.1 and 401.9

Case-Mix Adjustment Variables and Scores (Note: 4-Equation Model was Estimated on Episodes from 2005 where 401.1 and 401.9 were not counted in the Hypertension Diagnosis Group)					
	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
CLINICAL DIMENSION					
1	Primary or Other Diagnosis = Blindness/Low Vision	3	3	3	3
2	Primary or Other Diagnosis = Blood disorders	2	5		
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms	3	8	3	10
4	Primary Diagnosis = Diabetes	5	13	1	8
5	Other Diagnosis = Diabetes	3	5	1	5
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	2	6		6
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)		6		
8	Primary or Other Diagnosis = Gastrointestinal disorders	2	6	1	5
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2	2			

Case-Mix Adjustment Variables and Scores (Note: 4-Equation Model was Estimated on Episodes from 2005 where 401.1 and 401.9 were not counted in the Hypertension Diagnosis Group)					
	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
10	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, OR Neuro 2 - Peripheral neurological disorders, OR Neuro 3 - Stroke, OR Neuro 4 - Multiple Sclerosis			2	
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	3	6	1	7
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	3	8	5	8
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more	3	10	3	10
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis OR Neuro 2 - Peripheral neurological disorders ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1	4	1	2
15	Primary or Other Diagnosis = Neuro 3 - Stroke		2		
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1	3	2	8
17	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1860 (Ambulation) = 4 or more	1	5		
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis ***AND AT LEAST ONE OF THE FOLLOWING:*** M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more ***OR*** M1850 (Transferring) = 2 or more ***OR*** M1860 (Ambulation) = 4 or more	3	3	12	18

Case-Mix Adjustment Variables and Scores (Note: 4-Equation Model was Estimated on Episodes from 2005 where 401.1 and 401.9 were not counted in the Hypertension Diagnosis Group)					
	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	2			
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	5	5		
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression	4	6	2	6
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders	1	3		3
23	Primary or Other Diagnosis = Pulmonary disorders	1	5	1	5
24	Primary or Other Diagnosis = Pulmonary disorders ***AND*** M1860 (Ambulation) = 1 or more	1			
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	10	20	8	20
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	6	6	4	4
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications OR Skin 2 – Ulcers and other skin conditions ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	2		2	
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	6	12	5	12
29	Primary or Other Diagnosis = Tracheostomy	4	4	4	
30	Primary or Other Diagnosis = Urostomy/Cystostomy	6	22	4	22
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	8	15	5	11
32	M1030 (Therapy at home) = 3 (Enteral)	4	11		11
33	M1200 (Vision) = 1 or more	1			2
34	M1242 (Pain)= 3 or 4	1			

Case-Mix Adjustment Variables and Scores (Note: 4-Equation Model was Estimated on Episodes from 2005 where 401.1 and 401.9 were not counted in the Hypertension Diagnosis Group)					
	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
35	M1308 = Two or more pressure ulcers at stage 3 or 4	3	3	5	5
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	5	11	5	11
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	16	26	12	22
38	M1334 (Stasis ulcer status)= 2	7	7	7	7
39	M1334 (Stasis ulcer status)= 3	11	11	11	11
40	M1342 (Surgical wound status)= 2		2	3	
41	M1342 (Surgical wound status)= 3	4	4	4	4
42	M1400 (Dyspnea) = 2, 3, or 4	2	2		
43	M1620 (Bowel Incontinence) = 2 to 5	1	2	1	
44	M1630 (Ostomy)= 1 or 2	5	9	3	9
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3	0	1	2	3
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	2	4	2	2
47	M1830 (Bathing) = 2 or more	3	3	6	6
48	M1840 (Toilet transferring) = 2 or more	2	3	2	
49	M1850 (Transferring) = 2 or more		1		
50	M1860 (Ambulation) = 1, 2 or 3	1		1	
51	M1860 (Ambulation) = 4 or more	3	3	4	5

Notes: The data for the regression equations come from a 20 percent random sample of episodes from CY 2005. The sample excludes LUPA episodes, outlier episodes, and episodes with SCIC or PEP adjustments.

Points are additive, however, points may not be given for the same line item in the table more than once.

Please see Medicare Home Health Diagnosis Coding guidance at http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp for definitions of primary and secondary diagnoses.

TABLE 4: The Difference in Points between the Current and Proposed Case-mix Adjustment Scores

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision	0	0	0	0
2	Primary or Other Diagnosis = Blood disorders	0	0		
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms	-1	1	0	0
4	Primary Diagnosis = Diabetes	0	1	0	0
5	Other Diagnosis = Diabetes	1	1	0	1
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	0	0		0
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)		0		
8	Primary or Other Diagnosis = Gastrointestinal disorders	0	0	0	1
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2	-1			
10	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, OR Neuro 2 - Peripheral neurological disorders, OR Neuro 3 - Stroke, OR Neuro 4 - Multiple Sclerosis			0	
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	0	-1	0	-1
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	0	0	0	0
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more	0	0	0	0
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis OR Neuro 2 - Peripheral neurological disorders ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	-1	0	-1	0
15	Primary or Other Diagnosis = Neuro 3 - Stroke		1		
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	0	0	0	0

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
17	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1860 (Ambulation) = 4 or more	0	0		
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis ***AND AT LEAST ONE OF THE FOLLOWING:*** M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more ***OR*** M1850 (Transferring) = 2 or more ***OR*** M1860 (Ambulation) = 4 or more	0	0	0	0
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	0			
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	0	0		
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression	1	1	0	1
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders	0	1		1
23	Primary or Other Diagnosis = Pulmonary disorders	0	0	0	0
24	Primary or Other Diagnosis = Pulmonary disorders ***AND*** M1860 (Ambulation) = 1 or more	0			
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	0	0	0	0
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	0	0	0	0
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications OR Skin 2 – Ulcers and other skin conditions ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	0		0	

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	0	0	0	0
29	Primary or Other Diagnosis = Tracheostomy	0	0	0	
30	Primary or Other Diagnosis = Urostomy/Cystostomy	0	-1	0	-1
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	0	0	0	-1
32	M1030 (Therapy at home) = 3 (Enteral)	0	-1		-1
33	M1200 (Vision) = 1 or more	0			1
34	M1242 (Pain)= 3 or 4	0			
35	M1308 = Two or more pressure ulcers at stage 3 or 4	0	0	0	0
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	0	0	0	0
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	0	0	0	-1
38	M1334 (Stasis ulcer status)= 2	-1	-1	-1	-1
39	M1334 (Stasis ulcer status)= 3	0	0	0	0
40	M1342 (Surgical wound status)= 2		0	0	
41	M1342 (Surgical wound status)= 3	0	0	0	0
42	M1400 (Dyspnea) = 2, 3, or 4	0	0		
43	M1620 (Bowel Incontinence) = 2 to 5	0	0	0	
44	M1630 (Ostomy)= 1 or 2	0	0	0	0
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3	-1	0	0	-1
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	0	0	0	0
47	M1830 (Bathing) = 2 or more	0	0	0	0
48	M1840 (Toilet transferring) = 2 or more	0	0	0	
49	M1850 (Transferring) = 2 or more		-1		
50	M1860 (Ambulation) = 1, 2 or 3	0		0	
51	M1860 (Ambulation) = 4 or more	0	-1	0	0

Notes: The data for the regression equations come from a 20 percent random sample of episodes from CY 2005. The sample excludes LUPA episodes, outlier episodes, and episodes with SCIC or PEP adjustments.

Points are additive, however points may not be given for the same line item in the table more than once.

Please see Medicare Home Health Diagnosis Coding guidance at http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp for definitions of primary and secondary diagnoses.

BILLING CODE 4120–01–C

In the CY 2012 HH PPS proposed rule, we also stated that we examined how episodes in the sample shifted into a different clinical severity level when going from a four-equation model that includes 401.1 and 401.9 to a four-equation model that does not include 401.1 and 401.9. It should be noted that a small number of episodes also changed functional groups. In our analysis, we looked at the distribution

of episodes in each clinical severity level (low, medium, high) by the four-equation model indicators (early/late episodes and low/high therapy episodes). When comparing the distribution of episodes using the four-equation model without the 401.1 and 401.9 hypertension codes to the distribution of episodes using the four-equation model with the hypertension codes (our current four-equation model), there was a similar distribution of episodes between the low, medium and high clinical levels, for each of the four-equation model indicators. We also looked at the distribution of episodes in each functional severity level by the four-equation model indicator. There was also a very similar distribution of episodes for the three functional severity levels using the four-equation model without the two hypertension codes compared to the distribution of episodes using the current four-equation model, for each of the four-equation model indicators. Since the four-equation model without the hypertension codes 401.1 and 401.9 had similar clinical and functional distributions of episodes as the current model, we decided that it was not necessary to change the thresholds for the clinical and functional severity levels.

We revised the payment regression model using the clinical and functional severity groups constituted after removal of the hypertension codes. In addition, as we described in the proposed rule, at this stage of case-mix system redevelopment, we decided to implement a revision of the weights using a new method of decelerating therapy resources with higher numbers of therapy visits. The new method involved the removal of the therapy visit step indicators from the payment regression model (a step indicator is a subgroup of episodes defined by a range of therapy visits, such as 7 to 9 therapy visits). This approach has the advantage of staging the introduction of clinical and functional severity levels into the model as a separate step, to avoid excessive influence on the clinical and functional effects from numerous therapy step variables that would otherwise be simultaneously entered into the regression. In other words, we eliminated the therapy visit step indicators from the payment regression model to ensure that more of the resource use would be captured by clinical and functional variables, rather than therapy variables. Later, we implemented a method to account for the resource use for the therapy step variables. The new payment regression model that was developed estimated the relationship between an episode's total resource cost (as measured in dollars corresponding to wage weighted minutes) and the clinical severity indicators, functional severity indicators, and four-equation indicators (early/late episodes and low/high therapy services).

It should be noted that for the payment regression model, we used data from 2007, which is the most recent data available before the implementation of the HH PPS refinements. The coefficients for the payment regression model using 2007 data can be found in Table 5. The adjusted R-squared value for the payment regression model using 2007 data is 0.3769.

BILLING CODE 4120–02–P

TABLE 5: Payment Regression Model

Variable Name	Variable Description	New Payment Regression Coefficients
clin_grp2_1	Step 1, Clinical Score 5 to 8	$6.55
clin_grp3_1	Step1, Clinical Score 9 or More	$37.72
func_grp2_1	Step 1, Functional Score = 6	$88.99
func_grp3_1	Step1, Functional Score 7 or More	$129.81
clin_grp2_21	Step 2.1, Clinical Score 7 to 14	$87.49
clin_grp3_21	Step 2.1, Clinical Score 15 or More	$191.74
func_grp2_21	Step 2.1, Functional Score = 7	$43.63
func_grp3_21	Step 2.1, Functional Score 8 or More	$65.49
clin_grp2_22	Step 2.2, Clinical Score 9 to 16	$76.41
clin_grp3_22	Step 2.2, Clinical Score 17+	$177.93
func_grp2_22	Step 2.2, Functional Score = 8	$36.55
func_grp3_22	Step 2.2, Functional Score 9 or More	$109.94
clin_grp2_3	Step 3, Clinical Score 3 to 5	$28.53
clin_grp3_3	Step 3, Clinical Score 6 or More	$112.15
func_grp2_3	Step 3, Functional Score = 9	$73.68
func_grp3_3	Step 3, Functional Score 10 or More	$113.33
clin_grp2_4	Step 4, Clinical Score 8 to 14	$84.62
clin_grp3_4	Step 4, Clinical Score 15 or More	$213.78
func_grp2_4	Step 4, Functional Score = 7	$73.13
func_grp3_4	Step 4, Functional Score 8 or More	$133.71
step2_1	Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	$386.71
step2_2	Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	$413.85
step3	Step 3, 3rd+ Episodes, 0-13 Therapy Visits	-$63.66
step4	Step 4, All Episodes, 20+ Therapy Visits	$700.20
_cons	Intercept	$348.74

Note: The data for the payment regression model come from a 20 percent random sample of episodes from 2007.

The raw weights for each of the 153 groups were then calculated based on the payment regression model. It should be noted that the raw weights do not change across the graduated therapy steps between the therapy thresholds. In the next step of weight revision, the weights associated with 0 to 5 therapy visits were increased. The weights associated with 14–15 therapy visits were decreased and the weights associated with 20+ therapy visits were further decreased as well. These adjustments were made to discourage inappropriate use of therapy while addressing concerns that non-therapy services are undervalued. As stated in the CY 2012 HH PPS proposed rule, the larger reduction factor for episodes with 20 or more therapy visits compared to the reduction factor for episodes with 14 to 15 therapy visits implemented a more aggressive deceleration than we used in the current weights. Currently, there is a high payment weight associated with the 20 or more therapy visit threshold to capture the costs associated with providing 20 therapy visits, as well as numbers of therapy visits well beyond 20 therapy visits. As a result, there is a large increase in the payment weight between the 18–19 therapy visit step and the 20 or more therapy visit threshold. This large increase in the payment weight may create incentives for agencies to provide unnecessary therapy visits to reach the 20 therapy visit threshold, and may explain MedPAC's observation that there was a larger increase in the number of episodes in the 20 or more therapy visit group than the 14 or more therapy visit group. By implementing a larger reduction to episodes with 20 or more therapy visits, we will provide a disincentive for agencies to pad episodes just to 20 visits or slightly more, to be able to realize a large margin from that threshold, which was designed to pay for not only episodes involving 20 or just above 20 therapy visits, but also episodes involving considerably more than 20 therapy visits.

After the adjustments were applied to the raw weights, the weights were further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same

clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds were gradually increased. We did this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We used a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) was constant. The interpolated weights were then normalized so that the average case-mix weight in the 2007 sample was equal to 1.

After applying the adjustments to the raw weights, applying the interpolation between the therapy thresholds, and normalizing the weights so that the average case-mix for the weights was equal to 1 in the 2007 sample, we applied a budget neutrality factor to the weights to ensure that the case-mix weights result in aggregate expenditures in 2009, which was the most current and complete data available to us, equal to expenditures using the current payment weights. It is important to note that our authority allows us to reduce home health payments only as described in section 1895(b)(3)(B)(iv) of the Act. As such, we must revise our payment weights in a budget neutral manner. Therefore, after deriving revised relative case-mix weights, we increased the weights to achieve budget neutrality to the most current, complete data available, which was 2009. In the CY 2012 proposed rule, as we described in section A of this final rule, we proposed to reduce payments under our authority in section 1895(b)(3)(B)(iv) of the Act to reduce the home health base episode payment to account for nominal case-mix growth through 2009.

We also noted that we would continue to evaluate and potentially refine the payment weights as new data and analysis became available. We discuss our new data, analysis, and changes to the proposed payment weights in our comment responses below.

The following is a summary of the comments we received regarding the proposal to revise the HH PPS case-mix weights.

Comment: Commenters stated that the levels of weight changes are more arbitrary than evidence based and it appears that CMS picked a level of adjustment rather than develop a real analysis of the differences in episode costs/resource use from episode reimbursement rates. Commenters stated that the proposal to increase and decrease therapy episode case-mix weights is not supported by any evidence that the therapy related episode case-mix weights have a different relative resource cost today than they did in 2008 when CMS implemented the refinements. The commenters also stated that there is no resource cost change rationale for the proposed change in case-mix weights. In addition, commenters stated that they would like the data to directly show that the resource costs justify the specific adjustments proposed. Some commenters stated that if the payment model improperly incentivizes the provision of therapy care with higher than warranted payment rates, there should be data available to show the extent to which therapy episodes are overpriced and what level of payment would be appropriate. Commenters suggested that CMS undertake a study to provide additional rationale for the proposed adjustments to the case-mix weights.

Response: As we stated in the CY 2012 HH PPS proposed rule, we believe that MedPAC has provided strong evidence that our reimbursement for episodes with high therapy is too high. Also, based on MedPAC's analysis and our own findings, we believe that the resource costs reflected in our current case-mix weights for therapy episodes, in particular for those episodes with high amounts of therapy, are too high and that an adjustment to the HH PPS therapy case-mix weights is warranted.

In the proposed rule, we stated that we would continue to analyze therapy resource costs as more current and complete data became available. Since the publication of the proposed rule, complete 2009 CR data and partial 2011 claims data, which include the new therapy G-codes, have become available. These data have enabled us to expand on MedPAC's and our analysis for this final rule.

We performed a variety of analyses to look at the resource costs of home health episodes, particularly those episodes with high therapy. As part of the analysis, we have developed methods to examine cost data from freestanding HHAs' MCRs for FY 2009. The methodology involves an initial screening for incomplete and questionable data (for example, extreme ratios of payments to costs) similar to MedPAC's ''trimming'' methodology and two additional trims, one which excludes providers whose Medicare home health outlier payments exceeded 10 percent of their total Medicare home health payments and another which trims extreme values at the top and bottom 1 percent of the distribution of costs per visit for each discipline. We excluded providers whose Medicare home health outlier payments exceeded 10 percent of their total Medicare home health payments because in CY 2010 rulemaking, we found an association between high outlier payments and providers with questionable billing practices. We note that since only non-audited MCRs are available, we found it necessary to perform trims to ensure reasonably accurate cost estimates. Using the trimmed MCRs, we developed agency specific costs per visit for each discipline. In the sample of 4,309 MCRs, if a particular agency's cost-per-visit for a discipline was trimmed out when the trimming methodology was applied to the MCRs, the average cost-per-visit for all MCRs in the sample was used for that agency. For example, if a MCR had a value for the cost-per-visit for physical therapy that was in the top or bottom 1 percent of the distribution of cost-per-visits for physical therapy, that value would be imputed as the average cost-per-visit from values retained in the data after trimming. If any agency needed all 6 discipline costs-per-visits imputed, its MCR was excluded from the dataset. We imputed the cost-per-visit using the average cost-per-visit in approximately 10 percent of instances. Most of the imputations involved occupational therapy, speech therapy, and medical social work, which together account for a relatively small share of visits. Combined these three disciplines accounted for only 1.5 visits out of total visits per episode, which averaged 18.8 visits in 2009.

The file preparation procedure described above resulted in a dataset consisting of 4,309 MCRs from freestanding agencies in 2009, approximately half the number in the original MCR file. Most of the losses occurred at the initial screening stage (incomplete and questionable data). We examined characteristics of the agencies represented in the final sample, and found that distributions in the original and final samples were very similar. Unsurprisingly, however, small agencies (with fewer than 95 episodes) were nearly halved as a proportion of all agencies represented in the MCRs; they accounted for approximately 7.5 percent of the MCRs we used. These agencies tended more often to have incomplete or questionable data in their MCRs.

After developing agency specific costs per visit for each discipline, we merged the MCRs with 100 percent of the included providers' claims for 2009. We estimated the cost of each provider's

episodes by multiplying the number of visits, by discipline, by the average cost-per-visit, by discipline, calculated from the provider's MCR. Due to data incompleteness and reliability issues related to costs and payments for non-routine medical supplies (NRS), we did not include NRS in our estimate of the costs or payments.

We compared the costs of these episodes to their Medicare payment. Our analysis of the differences in episodes' costs and reimbursements suggests that payment on average exceeds costs by about 30-percent for normal episodes with 14 or more therapy visits. We defined normal episodes as non-LUPA, non-PEP, non-outlier episodes. Because the reimbursement for episodes with at least 14 therapy visits is high, the 30 percent estimate represents a large financial incentive. For instance, our analysis shows that in 2009, the average amount that payment exceeded cost for a normal episode with 14–19 therapy visits was more than $1100 (Table 6) and the average amount that payment exceeded costs for a normal episode with 20 or more therapy visits was more than $1500 (Table 7). We note that the average amount that payment exceeded costs for a normal episode with 1 to 5 therapy visits was around $300. Ideally, we wish to avoid marked differences in the amount that payment exceeds costs for different types of episodes to lessen the incentive to admit certain types of patients to maximize Medicare reimbursements.

TABLE 6: Episodes with 14-19 therapy visits

Type of episode		Estimated average cost	Estimated average payment	Estimated payment excess as proportion of cost	Amount that payment exceeds cost per episode
Normal	**Mean**	$3,730	$4,843	29.8%	$1,113
	Median	$3,560	$4,805	35.0%	$1,245

TABLE 7: Episodes with 20+ therapy visits

Type of episode		Estimated average cost	Estimated average payment	Estimated payment excess as proportion of cost	Amount that payment exceeds cost per episode
Normal	**Mean**	$5,231	$6,811	30.2%	$1,579
	Median	$4,964	$6,713	35.2%	$1,749

Normal episodes are defined as non-LUPA, non-PEP, non-outlier episodes. The analysis was run on a 100% sample of 2009 claims and based on 2009 dollars. The table is based on a sample of 4,309 providers.

We conducted a simulation to examine our proposal's impact on margins and profit for different categories of episodes, using the data from the MCR providers that was also found in the 20 percent sample of 2009 claims from which we estimate the proposed rule's reimbursement impacts. The analysis was based on 3,361 providers whose MCR period was precisely matched to the time period covered by the claims (that is, MCR periods had to begin and end in 2009). Although this sample was smaller than the cleaned CR sample from which we estimated per-episode costs and payments in 2009, the distributions of provider characteristics were changed little by the reduction in agencies. The simulation incorporated the proposed payment weights and the other payment parameters in our proposal (that is, a 5.06 percent payment reduction due to nominal case-mix growth, the wage index, and rate updates). The simulation updated the costs of episodes to 2012 dollars using the market basket increase and estimated the payment for episodes in terms of 2012 dollars. This analysis suggested that all episodes would have payments in excess of estimated costs, except for some episodes in the 20 or more therapy visit group. We note that about half of the episodes with 20 or more therapy visits would break even or retain a positive margin under the proposed revised case-mix weights. About 6 percent of episodes nationally in 2009 had 20 or more therapy visits. However, the results of this analysis also indicated that the revised case-mix weights in the proposed rule would result in episodes with 14 or more therapy visits having considerably less payments in excess of estimated costs than episodes with less than 14 therapy visits.

We note that our analyses of the costs to reimbursement for high therapy episodes clearly indicates that we are currently overpaying for these episodes and we believe an adjustment to the case-mix weights for high therapy weights is necessary. However, based on the results of our simulation analysis on our proposed weights, we decided to test whether a different set of payment

adjustment factors would result in more even payments in excess of estimated costs across therapy and non-therapy episodes. As stated in the proposed rule, we examined a number of different sets of adjustments when developing the payment weights. One of the sets of adjustments was an adjustment where the weights associated with 0 to 5 therapy visits were increased by 3.75 percent, the weights associated with 14–15 therapy visits were decreased by 2.5 percent, and the weights associated with 20+ therapy visits were decreased by 5 percent. We applied this set of adjustments in the same manner as the adjustments we originally proposed. When re-running the simulation analysis on these new weights, we saw relatively even payments in excess of estimated costs across the various types of episodes, including episodes with 14–19 therapy visits, episodes with 20–25 visits, episodes with low therapy, and non-therapy episodes. It should be noted that episodes with 26 or more therapy visits did not have payments in excess of estimated costs; however, we believe there are efficiencies used when providing these high therapy episodes and that the costs we estimated for these episodes are higher than actual costs. In addition, some of these high therapy episodes may be eligible for outlier payments. As a result of the findings from the simulation analysis, which show relatively even payments in excess of estimated costs across episodes, we are finalizing these new weights created using the new adjustment factors.

We note that for future rulemaking, we plan to do further analysis using audited CRs, if available, and data on the use of therapy assistants (G-code data) and we plan to make adjustments accordingly. In the CY 2011 HH PPS final rule, we finalized a requirement that HHAs report G-codes on the HH PPS claims which differentiate therapy provided by a qualified therapist versus therapy provided by a therapy assistant. We have preliminary data using claims from early in the period after reporting of the G-codes began in 2011. We have assessed how the percentages of therapy provided by a therapy assistant vary relative to the quantity of therapy provided. In our analysis, we looked at claims which had a start date on or after April 1, 2011 and examined the percentage of therapy provided by therapy assistants for various levels of therapy, such as episodes with 1–5 therapy visits, 6–9 therapy visits, 10–13 therapy visits, 14–19 therapy visits, and 20+ therapy visits. In addition, we looked at the percentages of therapy provided by therapy assistants when episodes from all providers were included and when episodes from providers in areas where suspect billing practices are relatively widespread were excluded. The results from these two analyses were similar.

Table 8 shows the percentage of therapy visits provided by therapy assistants when providers in areas associated with suspect billing practices are excluded. The overall results suggest that on average our assumptions, built into the resource cost estimates concerning the share of physical therapy assistants in the labor force are somewhat lower than reported so far in the G-code data. In 2007 (the data year used to estimate the payment regression leading to the relative weights), the assumption concerning the proportion of the labor share for physical therapy assistants was 17 percent. The national average in the initial G-code data for physical therapy assistants is 22.1 percent. For occupational therapy, the results were different. The assumption concerning the labor share proportion for occupational therapy assistants was 12 percent, while the national average in the G-code data for occupational therapy assistants is very similar, 11.8 percent.

Further results from the G-code data show that there is variation in the percentage of physical therapy provided by therapy assistants and the percentage of occupational therapy provided by therapy assistants when different levels of therapy are provided. The initial G-code data suggest the percentages of physical therapy visits provided by therapy assistants for episodes with 14–19 therapy visits and 20+ therapy visits are 25.9 percent and 29.0 percent, respectively. We note that these results seem to indicate that providers may be using more therapy assistants for episodes with high therapy, and therefore, the costs for these high therapy episodes may be even less than what was reflected in our earlier cost-to-reimbursement analyses. Furthermore, we note that the OES data produced by the Bureau of Labor Statistics showed that in 2009, 20 percent of physical therapy was provided by therapy assistants and that 16 percent of occupational therapy was provided by therapy assistants.

TABLE 8: Percentage of Therapy Provided by Therapy Assistants for Episodes with Different Levels of Therapy

Category (therapy visits in episode)	All therapy visits	Physical therapy visits	Occupational therapy visits	Speech therapy visits	PT ass't percent	OT ass't percent
1 TO 5	89,934	77,400	10,903	1,631	10.1	3.4
6 TO 9	213,234	189,824	20,843	2,567	20.2	7.6
10 TO 13	192,207	160,405	28,861	2,941	25.6	11.6
14 TO 19	133,840	99,731	30,329	3,780	25.9	13.0
20+	86,094	52,031	28,215	5,848	29.0	16.9
TOTAL	715,309	579,391	119,151	16,767	22.1	11.8

We believe our analysis of the G-codes indicates that the new adjustments to the case-mix weights may be conservative. We have decided to use a conservative approach while we wait for more complete data. We will continue to analyze data as they become available and may make further adjustments to the case-mix weights if necessary.

Comment: Commenters stated that CMS should develop the necessary objective clinical and financial data to support any change in case-mix weights for therapy related episodes prior to

implementing any change in the weights. Commenters recommended that CMS limit changes to those that have a reliable and transparent base in evidence. Another commenter recommended that CMS refrain from methodology which only shifts reimbursement to different parts of the model and instead focus on working with the industry to make more substantive and appropriate changes that stabilize home care reimbursement and provides more accurate payment. The commenter stated that payment cuts and methodology changes that can influence clinical behavior have not been successful at accurately paying for therapy services and may have disproportionately harmed providers that are providing appropriate levels of care.

Response: We wish to point out to commenters that our revised approach to deriving weights for therapy-related episodes shares a fundamental commonality with the method used to derive the weights currently. As we described in our CY 2008 proposed and final regulations (72 FR 25363 and 72 FR 49764), in the four-equation model regression equation, we imposed a deceleration in the marginal increase in resources with each added therapy visit. We did this by imposing restrictions on the coefficients of the therapy visit variables during regression estimation. In fact, data analysis before imposing those restrictions showed no clear trend for the trajectory of growth in resources as therapy visits increased. Thus, the data did not provide a sensible guide. Commenters seem to assume that ''objective'' clinical and financial data would provide a clear answer for modeling resources in therapy-related episodes, but this isn't necessarily the case. We decided that a declining amount for marginal resources is appropriate in view of the need to address incentives to overuse therapy. After observing unexpected increases in episodes of 14 or more therapy visits, as well as other evidence and analysis bearing on the profitability of those categories of episodes, we sought a more aggressive approach.

We pursued a data-driven approach at many decision points in this year's modeling procedure. We examined the results from various perspectives, including graphically. The main impact of the changes to our modeling procedure was generally to dampen the upward slope of the weights. Please refer to the Abt report ''Revision of the Case-Mix Weights for the Home Health Prospective Payment System Report'' located at *http://www.cms.gov/center/hha.asp* for additional information about the trends in the weights.

In addition, our methodology was designed to be budget neutral. Our intention was to redirect resources to groups in accordance with updated information on resource use, to avoid having therapy resources dominate the results of the resource modeling procedure, and to reduce incentives to provide higher numbers of therapy visits than would be clinically indicated. We would be concerned that an approach which, as recommended by commenters, depends on negotiation with providers would stray too far from the data in the absence of clear consensus about how to treat patients in different situations.

Our simulation of profits suggests that our proposals move away from gross overpayment for high therapy cases to more even payments in excess of estimated costs across episodes with varying levels of therapy. We understand that in occasional circumstances this approach may be interpreted to mean that clinicians no longer would enjoy decision-making unfettered by cost considerations when faced with high-therapy-need patients. We wish to remind providers that utilization and cost data in health care contain a large random element; therefore, it is not possible to predict the cost of every case with the hoped-for precision. We anticipate that our current research, as provided for in Section 3131 of the Affordable Care Act, will ultimately advance the precision of our payment groups, and this mandate has involved and will continue to involve consultation with providers. However, at the current time we are obliged to use the data available to increase the accuracy of the HH PPS.

Comment: Commenters stated that CMS failed to take into account the greater administrative costs associated with providing high therapy visits.

Response: We do not have data in the MCRs or reliable data from commenters allowing us to estimate additional costs as mentioned in the comment. At this time, based on our data analysis described earlier in this section and MedPAC's analyses, we believe that a substantial incentive exists to provide increasing numbers of high-therapy episodes and we conclude that high therapy episodes are excessively overpaid.

Comment: Some commenters stated that they agree that the reimbursement for high therapy episodes is too high and that it is appropriate to adjust relative case-mix weights to better align resource use associated with care plans. Commenters stated that the proposed changes to the case-mix weights would improve access for patients who need non-therapy services and reduce the incentive to manipulate therapy visits to reap higher payments. Also, commenters stated that by reducing the overpayment associated with high therapy groups and redistributing it to lower therapy and other groups, CMS has encouraged more appropriate therapy use based on need. Furthermore, commenters stated that the proposed changes in the case-mix weights will help to decrease future nominal case-mix growth. Commenters believed that the proposed changes to the case-mix weights will reduce waste and help assure patients who need therapy will get the appropriate amount. Some commenters stated that they value the ongoing cooperation and collaboration on policy issues.

Response: We thank the commenters for their feedback and we appreciate the support.

Comment: Commenters stated that the case-mix weight changes are proposed to modify provider behavior by removing ''incentives'' for increased therapy utilization. They stated that the adjustments have the sole intent of changing clinical behavior for HHAs. Commenters stated that CMS should not use a payment model to direct clinical care planning and patient admission practices to address any concerns in care utilization.

Response: We disagree that our proposals are intended to force a change in clinical behavior. The purpose of the revision to the case-mix weights is to more accurately pay for services. We also wish to discourage provision of unnecessary therapy services and slow nominal case-mix growth. When we proposed and finalized the 153-group system, we stated our concern that clinical judgment had been overtaken by financial incentives. Subsequent utilization data showing a sudden shift in the proportion of episodes with very high numbers of therapy visits suggested that agencies were providing high amounts of therapy to maximize reimbursements. Since our simulations indicate that providers will be adequately or more than adequately paid for varying numbers of therapy visits within episodes, except perhaps in some cases for episodes with the highest numbers of therapy visits, we believe the proposed system of weights will be accommodating to clinical judgment.

Comment: Commenters stated that there should not be an across the board reduction in the payment for episodes with high therapy visits but rather CMS should conduct targeted medical review

so that those HHAs that are properly using therapy services are not punished for the actions of others. In addition, commenters stated that by implementing an across the board payment cut, agencies that have been more profitable may survive while agencies that have smaller margins may fail, thus potentially preserving those who may be committing abuse.

Response: Although 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. In addition, we would like to clarify that our method of adjusting the therapy-related episode weights did not result in an across the board reduction. Procedures we followed at the beginning of weight construction, based on 2007 data, resulted in a realignment of the weights. At the end of the weight construction process, we examined the change in weights and noted a wide range of differences in the weights, both positive and negative. Furthermore, we do not believe we are punishing agencies for the actions of others. The revision of the payment weights should result in relatively even payments in excess of estimated costs across various types of episodes, and therefore, result in more appropriate payment for services.

Comment: Commenters were concerned by the use of four year old data (data from 2007). Commenters stated that just as the 2008 data may be tainted due to the impact of the change in therapy thresholds, the 2005 data may also be tainted due to the impact of the 10-visit single therapy utilization threshold.

Response: We used 2007 data in our payment regression model because of our concerns about the reliability of the data from 2008 or later. In 2008, we implemented refinements to the HH PPS and our analysis showed an increase in nominal case-mix growth of about 4 percent, when previous years showed a case-mix growth of only 1 percent. In addition, MedPAC commented on a sudden change in the provision of therapy after the three therapy thresholds were implemented in 2008 and a decrease in episodes with no therapy. Due to these observations, we were concerned about using data from 2008 or later. We also described in our proposed rule that during the process of revising the case-mix weights, we originally re-estimated the payment regression model on 2008 data using the same dependent and independent variables as the payment regression model in our 2008 refinements and we compared the results to the current payment regression, which was based on 2005 data. We saw that if we were to use 2008 data in our payment regression to develop the weights, the regression would assign a higher relative resource cost to high therapy episodes and would assign a lower relative resource cost to episodes with little or no therapy than was assigned when deriving the current weights. Given MedPAC's conclusion that the payment system overvalues therapy and undervalues non-therapy episodes and the sudden change in the distribution of therapy episodes, we decided to use the most current pre-refinement data in our payment regression model, which was from 2007. We believe the 2007 data are more reflective of costs associated with patients' actual clinical needs than the 2008 and later data.

Comment: Commenters stated that there is no evidence that the level of therapy visits provided to patients is unnecessary. Commenters stated that CMS has not reviewed the claims involving the therapy visits to see if the level that was provided is unnecessary. Other commenters stated that there is no unnecessary utilization of therapy services by HHAs in their area and that the overuse of therapy services is a perception and not data based. They stated that therapy services are limited in their rural community and there are not enough therapists for HHAs to overutilize their services.

Response: The Senate Finance Committee recently performed an investigation of the nation's three largest home-health companies and found that ''they encouraged employees to make enough home-therapy visits to reach thresholds that triggered bonus payments, whether or not the visits were medically necessary'' (''Home-Health Firms Blasted'', October 3, 2011, Wall Street Journal, p. B1). In addition, our analysis showed a 1-year change in the distribution of therapy services in 2008 and showed that a significant portion of case-mix growth in 2008 and 2009 was due to the increased provision of therapy services. Furthermore, our analysis on the costs of high therapy services showed that the payment exceeds costs by 30 percent or more. Our analysis indicated that the average cost of episodes with 14–19 therapy visits and the average cost of episodes with 20+ therapy visits are more than $1100 and $1500 below Medicare reimbursement levels, respectively. Therefore, we believe there is a payment incentive to provide high therapy services and that certain agencies may be providing more therapy services to maximize reimbursement. The goal of the revision to the case-mix weights is to more accurately pay for services and since data indicates that we are overpaying for services, we are revising our weights to better reflect costs. In addition, based on our analysis of the costs and our predictions about the payment with the new case-mix weights, almost all episodes with high therapy will still be paid above costs and that payment under the new weights will result in more similar payments in excess of estimated costs across episodes with varying levels of therapy than our current weights, thereby encouraging more appropriate therapy use based on patient need rather than reimbursement.

Comment: Commenters suggested that CMS convene a technical expert panel of therapists and nurses to examine the appropriate use of all therapist assistants and nursing personnel in the home health benefit before implementing any changes to the HH PPS based on the premise that the utilization of therapy assistants is not clinically appropriate. One commenter provided examples of the use of therapy assistants. Commenters stated that there is no evidence to suggest that there is utilization of therapy assistants to increase the number of visits provided. Another commenter stated that the costs for therapy assistant services cannot be estimated by only looking at the assistant salary levels but also must include supervision time by the therapist and other related costs. Other commenters stated that therapy staffing agencies charge the same amount for therapist and therapy assistants, so some agencies don't see a decrease in costs. The commenter stated that since the OES data is not specific to Medicare home health, CMS should wait to review the data on G-codes and should wait to collect a year's worth of data before implementing any changes.

Response: Commenters are mistaken in concluding that our proposals assume that therapy assistants are inappropriately used in home health care. Our concern is that our reimbursement rates are too high in comparison to the actual costs incurred by providers, including costs related to recent shifts in the labor mix for therapy.

Our cost-to-reimbursement analysis used the average per-visit costs, inclusive of allocated overhead and the other costs of doing business for HHAs (except, as noted previously, NRS costs). The data available are not detailed enough to discern the drawing of resources to therapy assistant services as suggested by the commenter. Our analysis indicates that the average cost of episodes with 14–19 therapy visits

and the average cost of episodes with 20+ therapy visits are more than $1100 and $1500 below Medicare reimbursement levels, respectively, which leads us to believe that even given unrecognized costs for therapy assistant services, there would still be an inappropriate overpayment. Our OES data are limited to home health services, among which Medicare is the dominant payer for skilled services. The elements used in our rate-setting process come from national averages for firms in North American Industry Classification System (NAICS) Code 621600, Home Health Care Services. We do not know whether staffing agency practices as described by the commenter are widespread, but the data needed to incorporate reliably such information in resource cost estimates may be very difficult to develop. Although OES data also reflect services beyond Medicare's services, OES offers the most representative labor mix data available at this writing. We also note that analysis of preliminary G-code data shows a higher percentage of physical therapy provided by therapy assistants for episodes with high therapy than what is reflected in the OES data, and therefore, resource costs for episodes with high therapy may be less than the costs we used to develop our current proposed weights. We agree with the commenter that more accurate information on therapy labor mix will be available as a result of the G-codes and we may consider making future adjustments based on G-code information.

Comment: One commenter stated that there has been an increase in the past several years in therapy utilization and that only in recent years have they had adequate therapists to meet patient needs. In addition, the commenter stated that their HHAs only minimally use physical therapist assistants (PTAs) and certified occupational therapist assistants (COTAs) and that if CMS implements their new policies, their HHAs will be forced to reconsider/increase their use of PTAs and COTAs to survive.

Response: We are primarily concerned with increasing use of high numbers of therapy visits that may represent padding of the treatment plan to maximize reimbursement. Assuming the commenter's agency is meeting patient needs and is cost efficient, we see no reason why they would be induced to increase their use of PTAs and COTAs, especially if they think it would represent a decline in quality. We reiterate that our payment simulations show adequate payment relative to costs for all episodes, except for some episodes in the 20+ therapy group, which may be eligible for outlier payments.

Comment: A commenter stated that if CMS moves forward with the revision of the case-mix weights, then there should be a three-year phase-in to the new weights, beginning in 2012. The commenter stated that the phasing in would allow home care providers time to adjust to the financial consequences of the revised weights.

Response: Our analysis of the costs of episodes with high therapy suggests that the payments for normal 60-day episodes with 14–19 therapy visits may average approximately $1,100 more than the costs and the payments for normal 60-day episodes with 20+ therapy visits may average approximately $1,500 more than the costs. Given the large positive payments in excess of estimated costs suggested by these data, we believe that an adjustment to the weights is necessary and to phase-in or defer revising the weights any longer would be wasteful.

Comment: A commenter recommended that CMS adjust its proposed policy and continue to pay the current rates for certain groups such as those patients discharged from the hospital and entering their first or second episode of home health.

Response: Our method of weight construction takes account of the timing of the episode but it does not consider whether the patient was recently discharged from the hospital. We stopped using the patient's pre-admission location in the case-mix algorithm in 2008 because of difficulties agencies reported in obtaining accurate data and because the impact on resources was not clear in the 2005 data used for the model. We plan to revisit the role of pre-admission location as part of our study mandated by Section 3131 of the Affordable Care Act. This will be done in the context of studying various kinds of new data that might be used in payment adjustments, to ameliorate possible access problems.

Comment: Commenters stated that CMS has not examined the impact of the new proposed rule and cannot predict the effects of the implementation of the change in case-mix weights.

Response: We disagree with the commenter. As we described in responses to commenters earlier in this preamble, we have done simulations that show that the revised case-mix weights with the new adjustments would result in more similar levels of net reimbursements (payments in excess of estimated costs) across episodes than the net reimbursements resulting from our current weights. In addition, Section IV shows the projected impacts of all of our policies (including the payment reduction for nominal case-mix growth). These impacts represent a negative impact on reimbursements well within the Medicare margins that were estimated by MedPAC.

Comment: A commenter recommended monitoring quality outcomes and patient satisfaction after implementing these changes to ensure that the changes do not adversely affect patient care.

Response: We agree that tracking the indicators mentioned by the commenter is a good idea. We note that statistical information on quality outcomes is publicly available on the CMS Web site for commenters to study. We anticipate that patient satisfaction information will be added to home health compare data in the future. We intend to monitor the effect of all of the provisions of this final rule for unintended consequences.

Comment: Commenters stated that due to the therapy requirements implemented on April 1, 2011, there is less flexibility in using the therapy assistants.

Response: The therapy requirements implemented in the CY 2011 HH PPS final rule which require an assessment by a qualified therapist at the 13th and 19th visit were meant to confirm that the patient needs high therapy services and to ensure more involvement of qualified therapists in high therapy cases. 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) concluded that more therapy time spent with a qualified physical therapist, and less time with a physical therapy assistant, is more efficient and leads to better patient outcomes.

We note that according to our cost-to-reimbursement analysis, we are overpaying for high therapy services and we are finalizing with this rule an adjustment to the payment weights to more accurately pay for these services. We also note that preliminary analysis of G-code data from 2011, the same time period that the therapy requirements were implemented, shows a higher percentage of physical therapy provided by assistants for high therapy cases than is reflected in our current weights. We will be continuing to examine the trends in the G-code reporting going forward

and we plan to use the information in rate setting.

Comment: Commenters stated that CMS needs to analyze data to see whether their previous policies have addressed issues with the use of inappropriate therapy services before implementing the change in case-mix weights to address therapy issues. A commenter stated that it was not necessary to implement the payment reductions since CMS implemented the outlier policy and enhanced documentation requirements for therapy services.

Response: As stated earlier, the purpose of the revision to the case-mix weights is to more accurately pay for services. We customarily base payment revisions on the most recent data available, consistent with our judgment as to its integrity. At this time, the data indicate that CMS is paying for episodes with 14–19 therapy visits by an average of more than $1100 over the agencies' costs and is paying for episodes with 20+ therapy visits by an average of more than $1500 over the agencies' costs, and as such CMS is overpaying for high therapy cases. Previously implemented policies were intended to promote appropriate use of therapy and to increase the involvement of qualified therapists in high therapy cases to ensure that therapy is being provided in an efficient and effective manner. We again refer to the studies which described the improved patient outcomes with greater qualified therapist involvement. However, given that existing data show such high payments in excess of estimated costs for high therapy episodes, we believe an adjustment to the payment weights is necessary to more accurately pay for high therapy services.

Comment: Commenters stated that the Affordable Care Act provisions along with the payment reductions would leave a huge negative impact on HHAs and commenters suggested that CMS not implement their proposed changes to the case-mix weights.

Response: Our cost data show that we are paying too much for high therapy episodes, as our reimbursement exceeds costs by about 30 percent. We believe it is necessary to make adjustments to our case-mix weights to more accurately pay for high therapy episodes. Our simulation analysis indicates that the new, revised weights should still result in payments in excess of estimated costs for all high therapy episodes, except for some episodes in the 20+ therapy group. In addition, the new, revised weights should result in relatively even payments in excess of estimated costs across episodes with varying levels of therapy, as well as episodes with no therapy. As the Affordable Care Act provisions come into play, we will analyze reimbursement adequacy, as well as beneficiary access to services and make proposals accordingly.

Comment: Commenters urged CMS to expedite that comprehensive study of the case-mix system, to involve home health industry experts in the process, and to implement a revamped case-mix system by 2014.

Response: We have included industry representatives on the Technical Expert Panel meetings conducted under the Affordable Care Act Section 3131 research and demonstration project. Further data collection and analysis will be conducted over the coming two years. Please see Section G for an update on the status of the study.

Comment: Commenters stated that as an alternative to the adjustments to the weights, CMS should try to find cost savings by stopping overpayment to Medicare Advantage plans and suggested that CMS hold them accountable to the same Medicare Compare outcomes that HHAs must report.

Response: We disagree with the commenter's suggestion that CMS find cost savings by stopping overpayment to Medicare Advantage plans as an alternative to implementing adjustments to the weights. Our goal is to address the overpayment for high therapy services and we can only do so by adjusting the case-mix weights for high therapy cases. The goal of the revision of the case-mix weights is not to achieve a cost savings; we reiterate that the change in the case-mix weights is budget neutral. (In contrast, the case-mix adjustment to the national standardized amounts is intended to recover previous overpayments that resulted from coding practice changes.) The goal of the weight adjustments is to more appropriately pay for high therapy services given our findings about the costs for these services and MedPAC's request to address therapy vulnerabilities.

Comment: Commenters stated that the proposed case-mix weight changes would increase the weights assigned to episodes with no therapy visits; however, commenters stated that these non-therapy episodes have not had an increase in relative resource costs since 2008.

Response: In their 2011 Report to Congress, MedPAC suggested that HH PPS may ''overvalue therapy services and undervalue nontherapy services.'' MedPAC also stated that through their analysis of high and low margin agencies, they concluded that ''episodes with high case-mix values are overpaid and episodes with low case-mix values are underpaid.'' We also note that the non-therapy episodes tend to have a much higher rate of outlier cases than episodes with therapy, and therefore, HH PPS may not be sufficiently paying for some of these episodes. In addition, we conducted a preliminary analysis looking at the differences in costs relative to reimbursement across different types of home health episodes and different agency characteristics. The findings suggested that unprofitable episodes on average had significantly more skilled nursing, home health aide visits, and total visits than average, while they also had fewer therapy visits. Furthermore, the results suggested that therapy and post-acute care episodes were more likely to be more profitable than mutually exclusive subpopulations of non-therapy and community-referred episodes, respectively. Moreover, regarding the HHRG, less profitable episodes were slightly more likely to be assigned the lowest functional or service utilization severity level (that is, C1F1S1, C2F1S1, C3F1S1). We note that this analysis did have some limitations. One limitation was that nationally aggregated costs were used instead of individual agency costs. However, we believe that the findings of the preliminary analysis, along with our observations of the incidence of outliers, and MedPAC's findings indicate that the current system may undervalue non-therapy episodes.

Comment: Commenters stated by increasing the weights for non-therapy episodes, the proposal discourages HHAs to provide any therapy. They stated that the proposal will lead to an adverse discrimination against patients in need of therapy at all levels of need and utilization. They stated that they are concerned that the change in case-mix weights will discourage rehabilitation and patient self-sufficiency.

Response: We disagree with the commenters. Our data shows that we are currently overpaying for high therapy services. Also, we proposed to increase the weights for episodes with low therapy. Therefore, we do not believe that we are discouraging HHAs from providing therapy. We believe by more appropriately reimbursing for high therapy episodes, we are encouraging more appropriate therapy use based on patient need. We note that when projecting the payments for episodes with high therapy, payments are adequate and result in a profit, except on average for a small number of episodes with extreme levels of therapy, which in some cases may be eligible for outlier payments.

Comment: Commenters stated that there is a movement towards a multidisciplinary approach to care and utilization of broader ranges of therapy services to improve outcomes and that evidence based best practices have improved patient outcome scores. They stated that patients need a high number of therapy visits to implement the intervention practices, such as fall prevention. In a similar vein, other commenters stated that due to the use of interdisciplinary care, there is an increase in the provision of therapy and coordination between physical therapy, occupational therapy, and speech language therapy. They stated that proposed adjustments to the case-mix weights do not account for the cost of providing interdisciplinary care and they suggested that CMS and the home health community need to work together to develop a new system that accounts for the costs of the interdisciplinary patient care. Other commenters stated that OASIS data shows continued functional improvement in the status of home health patients and that HHAs are providing services well in excess of 20 visits in an episode despite the lack of increase in payment after 20+ visits. Commenters stated that CMS should not consider all of the change to the higher therapy groups as unnecessary.

Response: As part of our industry outreach efforts associated with the home health access study, we plan to solicit input from the industry regarding evidence pointing to the improved outcomes from the multidisciplinary approach, so that we can evaluate the strength of it. We have noted previously MedPAC's concerns with the validity of outcome measurement in home health care. In addition, we reiterate that we do not believe the new case-mix weights will disincentivize interdisciplinary patient care, as the payments for episodes with high therapy are still projected to exceed costs.

We also note that, as we described in the CY 2011 HH PPS final rule (75 FR 70390 through 70391), research shows a direct relationship between improved patient outcomes, and the percentage of therapy provided by qualified therapists. As previously described, 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) 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.

The commenter suggests that high therapy cases are the result of interdisciplinary care. While interdisciplinary therapy would increase the volume of therapy provided, we note that given the apparent high percentage of therapy assistants utilized in these episodes when compared to other therapy episodes, research would suggest that inefficiencies in care may be a factor in high therapy cases as well. Our current payments for these episodes would incentivize these inefficiencies. Additionally, as we have described in other comment responses, our simulation analysis shows that the revised weights will result in similar payments in excess of estimated costs for all episodes. As such, we believe we are lessening the incentive to provide particular types of episodes, while providing adequate reimbursements.

Comment: Commenters stated that CMS should institute safeguards to monitor discriminatory patient admission practices and misguided clinical care practices.

Response: We appreciate this comment but must point out that this is a costly and difficult task. Eventually, as a result of research mandated by the Congress in section 3131(d) of the Affordable Care Act, we hope to modify the HH PPS to lower the risk of discriminatory patient admission practices. As part of the outreach efforts for the section 3131(d) Affordable Care Act study, we plan to solicit comments on how we could launch a cost-effective effort without imposing unacceptable burdens on providers and patients. We also encourage continued efforts in the home health industry, aided by Medicare quality initiatives, to improve the consistency and appropriateness of clinical care plans and their implementation. In addition, we reiterate that based on our simulation analysis, we expect the new weights to result in similar payments in excess of estimated costs episodes and should therefore lessen discriminatory patient admission practices in home health.

Comment: Commenters advised CMS to analyze provider costs in 2011 and 2012 before implementing the change to the case-mix weights.

Response: Due to the lag in providers' preparation and submission of CRs, we do not have a complete set of data on provider costs for any given year until more than one year after the end of the year. As a result, the 2009 MCR data are the most current, complete cost data available. Given our analysis of the costs and payment for high therapy episodes using 2009 data, we believe that Medicare is overpaying for high therapy services by 30 percent or more. In addition, as we mentioned in a previous response, for our simulation analysis, we updated the costs of episodes to 2012 dollars using the market basket increase and estimated the 2012 payment for episodes. The simulation analysis using the new weights suggested that in 2012, the payment for episodes will still exceed costs and that there is a relatively even payments in excess of estimated costs across episodes, except for some episodes in the 20+ therapy group. We note that some of the episodes in the 20+ therapy group may be eligible for outlier payments.

Comment: Some commenters stated that the proposal to change the case-mix weights is premature and unproductive. Other commenters stated that CMS should dedicate their resources to develop a case-mix adjuster that does not use therapy utilization as a variable in determining payment; instead CMS should look into using patient characteristics to pay for therapy. Commenters stated that they would be supportive of any change in the case-mix weights that moves the model away from using utilization factors in determining payment.

Response: In their 2010 and 2011 Reports to Congress, MedPAC has urged us to address the therapy incentives in our payment system. We note that completely addressing MedPAC's concerns with the way we factor therapy services into our reimbursement will be a complex process, requiring comprehensive structural changes and a great deal of additional research and analysis. However, we believe there is evidence that we are overpaying for high therapy services and that it is appropriate to revise the case-mix weights now, to mitigate therapy vulnerabilities in the short term while we develop a longer term solution.

Comment: Commenters asked how CMS would check that the changes in

the case-mix weights would in fact be budget neutral. A commenter stated that in the past when changes in the HH PPS resulted in profits to the industry, CMS implemented a plan to recover the excess reimbursement. The commenter asked what would happen if the industry was under-reimbursed by the proposed changes, stating that in this situation, the proposed changes would not be budget neutral.

Response: We are uncertain what the commenter's concern is. As we described earlier in this section, we applied a budget neutrality factor to ensure that the new weights result in approximately the same aggregate expenditures as 2009, the most current data that were available. We equated the aggregate expenditures by setting the average of the case-mix weights under the new revised weights equal to the average under the current weights which we reimbursed in 2009. A slight difference between the aggregate totals remained, due to the effects of outlier payments. However, this difference amounted to only 0.01 percent. Also we reiterate that data shows that we are overpaying for high therapy services and we believe the new weights will more accurately align payment with costs. In addition, as stated in Section II.A, we will continue to assess real and nominal case-mix growth and if we were to see real case-mix growth increase more than the reported home health case-mix growth, we would increase payments accordingly. Furthermore, since the HH PPS began, the industry has never been under-reimbursed in the aggregate and when it was determined that certain LUPAs were on average under-reimbursed, we implemented the LUPA add-on to compensate for the underpayment.

Comment: A number of commenters stated that a failure to recalibrate the whole system weights would result in a change that was not budget neutral and Federal law prohibits changes in case-mix that are not budget neutral. Another commenter requested that CMS explain in detail the methodology used to develop the budget neutrality adjustment for the proposed case-mix weights.

Response: As stated in the proposed rule, to remove the two hypertension codes from our case-mix system, we needed to revise our case-mix weights to redistribute the dollars without reducing aggregate payments. To redistribute the dollars, we re-estimated the four equation models without codes 401.1 and 401.9. We then used the results from the four equation model to determine the clinical and functional severity level groups for each episode. This information was then used to estimate the payment regression model, which in turn was used to develop the weights. In addition, CMS has applied a budget neutrality factor of 1.2832 so that the new case-mix weights result in approximately the same aggregate expenditures as 2009. More details about the methodology used to ensure budget neutrality can be found in an updated version of the Abt Associates report ''Revision of the case-mix weights for the Home Health Prospective Payment System'' at *http://www.cms.gov/center/hha.asp.*

We also note that the payment reductions arising out of the nominal case-mix changes we have identified are not intended to be budget neutral (discussed in Section II.A). We reduce payment rates to account for nominal case-mix change.

Comment: CMS should publicly disclose the revised formula and factors employed in the calculation of a revised budget neutrality adjustment and provide an opportunity for public comment prior to finalization of the revised case-mix weights.

Response: We note that the Abt Associates report ''Revision of the Case-Mix Weights for the Home Health Prospective Payment System'' contains details about the methods used to achieve budget neutrality. This Abt Associates report was made publicly available around the same time that the CY 2012 HH PPS proposed rule was published. We have received comments on our methodology during this comment process. An updated version of this report will be made available at *http://www.cms.gov/center/hha.asp.*

Comment: Commenters stated that CMS should update its occupational mix assumptions in the 2012 refinements and that the increased use of therapy assistants should be reflected in the case-mix weights.

Response: We thank the commenter for their comment and we would like to clarify our methodology. As stated in the Abt Associates report ''Revision of the Case-mix Weights for the Home Health Prospective Payment System'' which can be accessed at *http://www.cms.gov/center/hha.asp,* the payment weights are based on wage-weighted time spent on home health visits in our sample. The wages come from estimates of the national hourly wage for six disciplines of home health care workers (skilled nursing, physical therapist, occupational therapist, speech language therapist, medical social services, and home health aides) from the Bureau of Labor Statistics Occupational Employment Survey (OES). When re-estimating the payment regression model on 2007 data, we used the wage-weighted minutes based on the 2007 OES data for average labor mix within each discipline and average hourly wages, including benefits. The 2007 OES labor mix for physical therapists is composed of 17 percent physical therapist assistants, 1 percent physical therapy aides, and 82 percent physical therapists. The 2007 OES labor mix for occupational therapists is composed of 12 percent occupational therapist assistants and 88 percent occupational therapists. The payment regression is modeling the wage-weighted time (resources) as predicted by the severity levels and therapy variables for early and later episodes, using 2007 claims. We note that before updating the labor mix in the wage-weighted minutes to more current data than 2007, we will wait for more complete G-code data. We will continue to assess the accuracy of our case-mix weights and may make adjustments in future rulemaking as more G-code data becomes available.

Comment: Commenters stated that CMS should calculate the budget neutrality adjustment to equate 2012 expenditures under the current and proposed case-mix weight models. Commenters recommended that CMS recalculate the budget neutrality adjustment to reflect the idea that HHAs have experienced some ''real'' case-mix change in 2010 and 2011 and will experience more in 2012.

Response: We applied a budget neutrality factor (1.2832) to the weights to ensure that the final proposed weights result in aggregate expenditures in 2009 approximately equal to expenditures using the current payment weights. We made the weights budget neutral to 2009 because the data from 2009 were the most current complete data available at the time. Using the most complete actual data available to achieve budget neutrality is a method consistent with case-mix weight recalibration methodology utilized by other Medicare payment systems. Similarly, the methodology is consistent with the method we have utilized since CY 2008 rulemaking to analyze and account for case-mix growth unrelated to real changes in patient acuity (nominal case-mix). Our current method assesses case-mix growth and reduces payment rates as warranted only after the claims data are complete. This method for both establishing budget neutrality in the weights and adjusting for nominal case-mix growth confines the correction on account of nominal case-mix growth to the rates while allowing the average case-mix level to evolve in the claims history without

intervention. However, the commenter's suggestion to project case-mix growth for future years is intriguing and we may consider such a methodology change in future rulemaking. Such a methodology change would allow us to project changes in case-mix based on expected trends in case-mix growth. It would also require us to make projections for payment adjustments to account for nominal case-mix growth based on trends. This projection method may be preferable to delaying the ability to account for future nominal case-mix increase. We believe that such a change in long-standing methodology would require rulemaking.

Our continued analyses of current claims data as they become available allows us to make adjustments to HH PPS case-mix weights as warranted, achieving budget neutrality using the most current complete data available, and account for growth in nominal case-mix as warranted.

Comment: Commenters stated that CMS explicitly proposes that the case-mix weight changes will affect clinical and patient admission behavior of HHAs. They stated that if the case-mix weight changes are implemented, the proportion of patient episodes with 14 or more therapy visits will decline and the proportion of non-therapy episodes will increase.

Response: Based on observation of sharp changes in distribution of episodes by the number of therapy visits, on information coming to us about provider practices in the field, as well as on analysis of margins in HH PPS, an effect on the behavior of HHAs would not be surprising.

Comment: The commenters stated that the therapy episodes have higher case-mix weights on average than non-therapy episodes so the reduction in the proportion of therapy episodes will reduce the average case-mix weight nationally and that failure to account for this behavioral change reduces the budget neutrality adjustment. Other commenters stated that the change in case-mix weights does not appear to be budget neutral because only 30 of the case-mix weight values increased while 123 of the case-mix weight values decreased from the current levels.

Response: To date, we have not incorporated forecasts of the sort indicated by the commenter in our budget neutrality adjustments. We may consider this for future rulemaking. However, we think that forecasting changes in the national case-mix average due to the utilization changes mentioned by the commenter would be difficult and perhaps not a reliable basis for payment. Regarding the positive and negative changes the case-mix weight values, we note that when developing the budget neutrality factor, we took into account the number of episodes in each HHRG along with the change in weights. We developed the factor so that the change in the weights would result in the same aggregate expenditures as 2009. One cannot only look at the increases or decreases in the case-mix weight values but one must also look at the degree of the change in the weights and the number of episodes associated with each of the weights when looking at budget neutrality. In general, the case-mix weight values that increased had higher volumes than the ones that decreased.

Comment: A commenter appreciated that the proposed changes to the case-mix weights are budget neutral.

Response: We thank the commenter for their support.

Comment: A commenter asked that CMS identify how the points from the hypertension 401.1 and 401.9 codes are reallocated in the proposed case-mix weight changes.

Response: The points are reallocated in the course of estimating the four-equation model's regression equation. In Table 3 shown above, we show the points associated with various clinical and functional variables based on the results of the four-equation model. The four-equation model is a linear regression explaining an episode's wage weighted minutes of care in the home as measured in dollars (the dependent variable) as a function of the episode's timing, therapy visits, clinical variable indicators (for example, pressure ulcer stage), and functional indicators (for example, limitation in bathing). After estimating the model, we determine the points associated with clinical and functional variables by dividing the coefficients by 10. By re-estimating the four-equation model on data without hypertension codes 401.1 and 401.9, we redistributed the points which would be associated with the two hypertension codes to other variables in the model. Table 4 shows the differences in points between the current and proposed case-mix adjustment scores. As stated in the proposed rule, for 13 of the 33 clinical and functional variables which had a different number of points, there was an extra point assigned when the two hypertension codes were excluded and for 20 of the 33 clinical and functional variables, there was one less point assigned compared to the current model.

Comment: Commenters stated that CMS presented strong and objective data indicating that an elimination of hypertension codes 401.1 and 401.9 was warranted. Commenters stated that they would like to see a comparable approach for therapy utilization. Other commenters stated that despite the data analysis of the resource costs of patients with hypertension codes 401.1 and 401.9, from a clinical viewpoint, there are still concerns that the removal of the hypertension codes might undervalue the resources need to address the needs of patients with hypertension.

Response: Our past exploration of modeling therapy elements of the case-mix in home health showed that predictive power is relatively low. MedPAC's recent results in their preliminary models of therapy elements are consistent with our experience. We will continue to study this issue. We remind the commenters concerned about removal of hypertension codes that our analysis showed that after the 153-group system went into effect, hypertension was no longer associated with marginal added resources. This was probably due to a big change in the frequency of reporting hypertension and meant that the average patient with hypertension (after accounting for other clinical conditions) was not as costly to care for as the average patient reported to have hypertension in 2005 (the year of the data that originally used to create the 153-group system). The new guidelines developed by the National Heart Lung and Blood Institute (NHLBI) concerning the appropriate reporting of these hypertension codes were released in late 2004. It is possible that prior to the NHLBI guidelines, HHAs were using codes 401.1 and 401.9 to reflect more severe hypertensive conditions. Our 2008 refinements analysis utilized 2003 data (prior to the NHLBI guidelines) and 2005 data (shortly after the guidelines release and likely prior to widespread adoption of them). As such, one probable reason that the 2008 refinements analysis identified these codes as more resource intensive, when more current data analysis does not, would be HHA use of these codes to reflect more severe hypertensive patients.

Comment: Commenters urged CMS to check that the removal of weights for the hypertension codes 401.1 and 401.9 is not premature and based on sound methodology. Commenters stated that coding experts believe that eliminating the two hypertension codes will result in up to a 7 percent decrease in coding-related reimbursement.

Response: In our proposal, we explained that the new point allocation from the re-estimated four-equation model redistributed resources across the other conditions in the model. Our other procedures for deriving the weights

were designed to maintain the effects of the redistribution. Therefore, a change in reimbursement for patients with the hypertension codes would in general not be 7 percent. The change for any given patient would depend on their combination of case-mix recognized conditions.

Comment: Commenters stated that CMS proposed to eliminate the codes 401.1 and 401.9 based on their concerns surrounding the new guidelines developed by the NHLBI.

Response: In addition to our concerns about changes in coding due to the new guidelines developed by the NHLBI, which we believe resulted in more accurate coding, we have also shown that the two hypertension codes are not associated with additional resources, and therefore, we are implementing the removal of these codes.

Comment: Commenters stated that there are certain areas where the increase in hypertension makes sense given the high prevalence of heart disease and obesity. Another commenter was concerned with the removal of hypertension from the case-mix system, stating that there may be external factors that CMS has not taken into account and that treatment of hypertension is an important part of home health.

Response: We thank the commenters for their comments. However, we note that we presented various analyses which showed that the two codes 401.1 and 401.9 are not associated with additional resource use. Therefore, we believe that the two codes should be removed from our case-mix system. However, we would like to clarify that we are not completely removing hypertension from our case-mix system; we are only removing codes 401.1 and 401.9. Currently, we believe that certain types of hypertension, such as hypertensive heart disease and hypertensive chronic kidney disease, are associated with additional resource use and should be included in our payment system; however, all of our analysis confirms that the two hypertension codes for benign essential and unspecified essential hypertension on average are not associated with additional resource use, and therefore, we are removing the codes to more accurately align payment with resource use.

Comment: Commenters stated that when changing or removing part of the model, CMS should perform the same comprehensive approach as it used for the 2008 refinements. The commenter stated that we should use the same criteria we used for the refinements to determine whether certain diagnoses codes and variables should be included in the model.

Response: As a result of research we are undertaking pursuant to Section 3131 of the Affordable Care Act, we plan a comprehensive re-examination of the variable set that is potentially available to us to use for case-mix and other payment adjustments. We decided to defer a comprehensive re-modeling effort until new and/or revised variables have been researched and can be tested. On OASIS, reported hypertension prevalence more than doubled between 2005 and 2008, the first year of the refined 153-group system. By 2008, hypertension prevalence was more than 60 percent. Given the large amount of coding change associated with hypertension, and the resulting extraordinary prevalence, we saw a need to revisit its impact on costs. The results indicated that for the average hypertension patient, the condition was not associated with a statistically significant increase in resources.

Comment: Commenters stated they would like to see CMS run the full, original regression models on test data from 2009 to see whether the indicators for hypertension codes 401.1 and 401.9 should be kept in the case-mix system. The commenters stated that after running the data, they would like to see the coefficients for the indicators for codes 401.1 and 401.9 from the full regression models for all 4 equations using the 2009 data.

Response: We did not pursue the commenters' suggestion, pending the outcome of ongoing research. We previously mentioned in this preamble concerns that data from 2008 and later reflect a large amount of nominal coding change. Without intensive work developing and reviewing current, discarded, and potentially new variables for the model, we would not necessarily arrive at an appropriate score for the hypertension variables. Also, we believe making significant scoring changes piecemeal (before a thorough review of potential variable sets) adds unacceptable burdens to administrative and HHA operations. We also note that re-estimating the full original regression models is not necessary to support our decision to remove the two hypertension codes. The reason is that we did re-run one multivariate regression models used to test the impact of the hypertension codes in our proposed rule. This model isolated the additional resources associated with codes 401.1 and 401.9 and is an additional analysis to that which we described in the proposed rule. When developing the proposed rule, we ran the test regression model controlling for the current weights because at the time, we had not yet developed the proposed weights. The results supported the removal of the codes. Table 9 shows the results of an updated test regression model. One can see the coefficients from the regression model of total resource use on the case-mix weight (using the refined revised case-mix weights that do not include the 401.1 or 401.9 diagnoses in calculating case-mix weight) and indicator variables for the presence of the 401.1 and 401.9 hypertension diagnoses. This equation is based on 2009 data with LUPAs and outliers excluded. The coefficients show that, controlling for the revised case-mix weights that we are finalizing in this rule, the presence of either a 401.1 or a 401.9 diagnosis is associated with significantly lower resource use. The mean value of the dependent variable is 543.17, so the magnitude of the coefficients is not particularly large, especially for the 401.9 diagnosis, but the results support dropping the two diagnoses from the case-mix calculation since they are not associated with higher resource use. We believe that this analysis along with the other analysis presented in the proposed rule support the removal of the two hypertension codes 401.1 and 401.9.

BILLING CODE 4120–01–P

TABLE 9: Parameter Estimates

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	**1**	-186.10324	0.77887	-238.94	<.0001
Case-mix weight (recalibrated)	**1**	539.86486	0.47910	1126.84	<.0001
ICD9 401.1 present	**1**	-7.07870	1.57995	-4.48	<.0001
ICD9 401.9 present	**1**	-2.91112	0.54903	-5.30	<.0001

In summary, as described in our response to comments, we are finalizing our proposal to revise the case-mix weights. Based on our analyses after the publication of the CY 2012 HH PPS proposed rule, we have refined the revision to the case-mix weights and the new adjustments to the case-mix weights can be seen in Table 10.

TABLE 10: Adjustments to the Raw Weights

Therapy step Group	New Adjustments
0 to 5 Therapy Visits	1.0375
14 to 15 Therapy Visits	0.975
20+ Therapy Visits	0.95

We reiterate that we used the same methodology described in the proposed rule when developing the new revised case-mix weights. To ensure that the revised weights result in approximately the same aggregate expenditures as we incurred in 2009, the budget neutrality factor applied to the weights changed slightly from 1.2847 to 1.2832. The new revised case-mix weights can be seen in Table 11.

BILLING CODE 4120–01–P

TABLE 11: Final Payment Weights (2007 sample)

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1	0.8186
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1	0.9793
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1	1.1401
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1	1.3008
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1	1.4616
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2	1.0275
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2	1.1657
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2	1.3039
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2	1.4421
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2	1.5804
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3	1.1233
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3	1.2520
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3	1.3807
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3	1.5094
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3	1.6381
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1	0.8340
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1	1.0302
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1	1.2265
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1	1.4228
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1	1.6190
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2	1.0429
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2	1.2166
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2	1.3903

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2	1.5641
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2	1.7378
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3	1.1387
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3	1.3029
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3	1.4671
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3	1.6313
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3	1.7956
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1	0.9071
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1	1.1348
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1	1.3624
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1	1.5900
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1	1.8177
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2	1.1160
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2	1.3211
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2	1.5262
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2	1.7313
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2	1.9364
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3	1.2118
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3	1.4074
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3	1.6030
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3	1.7986
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3	1.9942
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1	1.6223
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1	1.8331
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1	2.0438
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2	1.7186

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2	1.9496
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2	2.1807
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3	1.7668
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3	2.0252
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3	2.2836
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1	1.8153
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1	2.0224
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1	2.2294
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2	1.9116
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2	2.1389
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2	2.3663
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3	1.9598
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3	2.2145
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3	2.4691
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1	2.0453
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1	2.2682
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1	2.4911
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2	2.1415
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2	2.3848
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2	2.6280
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3	2.1897

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3	2.4603
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3	2.7309
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1	1.6822
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1	1.8730
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1	2.0638
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2	1.7628
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2	1.9791
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2	2.1954
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3	1.9247
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3	2.1305
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3	2.3362
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1	1.8508
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1	2.0460
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1	2.2412
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2	1.9314
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2	2.1521
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2	2.3729
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3	2.0933
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3	2.3035
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3	2.5136
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1	2.0747
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1	2.2878
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1	2.5009
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2	2.1553
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2	2.3940
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2	2.6326
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3	2.3172
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3	2.5453
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3	2.7734
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1	0.6692
30112	3rd+ Episodes, 6 Therapy Visits	C1F1	0.8718
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1	1.0744
30114	3rd+ Episodes, 10 Therapy Visits	C1F1	1.2770
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1	1.4796
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2	0.8421
30122	3rd+ Episodes, 6 Therapy Visits	C1F2	1.0263
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2	1.2104
30124	3rd+ Episodes, 10 Therapy Visits	C1F2	1.3945

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2	1.5787
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3	0.9352
30132	3rd+ Episodes, 6 Therapy Visits	C1F3	1.1331
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3	1.3310
30134	3rd+ Episodes, 10 Therapy Visits	C1F3	1.5289
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3	1.7268
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1	0.7361
30212	3rd+ Episodes, 6 Therapy Visits	C2F1	0.9591
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1	1.1820
30214	3rd+ Episodes, 10 Therapy Visits	C2F1	1.4049
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1	1.6278
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2	0.9091
30222	3rd+ Episodes, 6 Therapy Visits	C2F2	1.1136
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2	1.3180
30224	3rd+ Episodes, 10 Therapy Visits	C2F2	1.5225
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2	1.7269
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3	1.0022
30232	3rd+ Episodes, 6 Therapy Visits	C2F3	1.2204
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3	1.4386
30234	3rd+ Episodes, 10 Therapy Visits	C2F3	1.6568
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3	1.8751
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1	0.9324
30312	3rd+ Episodes, 6 Therapy Visits	C3F1	1.1609
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1	1.3893
30314	3rd+ Episodes, 10 Therapy Visits	C3F1	1.6178
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1	1.8463
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2	1.1054
30322	3rd+ Episodes, 6 Therapy Visits	C3F2	1.3154
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2	1.5254
30324	3rd+ Episodes, 10 Therapy Visits	C3F2	1.7353
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2	1.9453
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3	1.1985
30332	3rd+ Episodes, 6 Therapy Visits	C3F3	1.4222
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3	1.6460
30334	3rd+ Episodes, 10 Therapy Visits	C3F3	1.8697
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3	2.0935
40111	All Episodes, 20+ Therapy Visits	C1F1	2.2546
40121	All Episodes, 20+ Therapy Visits	C1F2	2.4117
40131	All Episodes, 20+ Therapy Visits	C1F3	2.5419
40211	All Episodes, 20+ Therapy Visits	C2F1	2.4364
40221	All Episodes, 20+ Therapy Visits	C2F2	2.5936

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3 = High)	Final Weights (using new adjustments)
40231	All Episodes, 20+ Therapy Visits	C2F3	2.7238
40311	All Episodes, 20+ Therapy Visits	C3F1	2.7140
40321	All Episodes, 20+ Therapy Visits	C3F2	2.8712
40331	All Episodes, 20+ Therapy Visits	C3F3	3.0014

BILLING CODE 4120–01–C

As stated earlier in our responses to comments, we performed a simulation analysis on the new revised weights. When re-running the simulation analysis on these new weights, we saw relatively even payments in excess of estimated costs across the various types of episodes, including but not limited to the episodes with 14–19 therapy visits, episodes with 20–25 visits, and non-therapy episodes. We note that in our analysis, we looked at various groups of episodes, such as non-therapy episodes, episodes with 1–5 therapy visits, episodes with 6–9 therapy visits, episodes with 10–13 therapy visits, episodes with 14–19 therapy visits and episodes with 20–25 therapy visits, as well as episodes with 26+ therapy visits. The analysis showed an even, similar payment in excess of estimated costs between almost all of the groups of episodes, except for episodes with 26+ therapy visits. We also note that in our sample, episodes with 20–25 visits are 64 percent of all of the episodes with 20+ therapy visits.

In addition, when performing a regression of the episode's total resource (dependent variable) using the new revised case-mix weights (independent variable), the R-squared value is 0.5436, which is slightly higher than the R-squared value for the proposed weights. As more data becomes available, such as G-code data and possibly audited CR data, we may further implement changes to the weights in future rulemaking.

C. Outlier Policy

1. Background

As we highlighted in our proposed rule (76 FR 41012), section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient home health (HH) care needs. In the proposed rule, we noted that prior to the enactment of the Affordable Care Act in March 2010, this section of the Act stipulated that estimated total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. We also provided historical milestones for the development of the outlier payment policy, including an overview of the July 2000 final rule (65 FR 41188 through 41190), in which we described the method for determining outlier payments.

As part of our proposed rule (76 FR 41013), we reiterated what was said in the CY 2010 HH PPS final rule (74 FR 58080 through 58087), in which we discussed excessive growth in outlier payments, the reasons for this growth, and our policy changes and methodologies to address it, which culminated in a 10 percent agency level outlier cap. We noted that this cap was implemented in concert with a reduced fixed dollar loss (FDL) ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent.

In our proposed rule (76 FR 41013), we also provided an overview of how the outlier payment percentage is determined and the relationship between the FDL and loss-sharing ratios.

At the time of the proposed rule, a preliminary look at partial CY 2010 Health Care Information System (HCIS) data showed total outlier payments to be 1.68 percent of total HH PPS payments. As such, we proposed to maintain the current FDL ratio of 0.67 until more recent and complete data became available on which to conduct further analysis.

As we stated in the proposed rule (76 FR 41013), we must deliver a Report to Congress regarding the results and recommendations of a home health study no later than March 1, 2014. Section 3131(d)(1)(A)(iii) of the Affordable Care Act requires the Secretary to analyze potential revisions to outlier payments to better reflect costs of treating Medicare beneficiaries with high levels of severity of illness.

2. Comments and Responses

The following is a summary of the comments we received regarding the outlier policies in the proposed rule.

Comment: Several commenters expressed general agreement with the methodology used to review the outlier policy, including possibly adjusting the fixed-dollar loss (FDL) ratio from its current value of 0.67 based on more current data becoming available. Many of these commenters urged CMS to refine its outlier policies to ensure access to care for Medicare beneficiaries, and also ensure that the full 2.5 percent of expected HH expenditures be spent on outlier payments. Some of these commenters noted that data presented by CMS showed less than 2.5 percent of outlier dollars were expended. Commenters also noted that outlier expenditures are less than prior years, reflecting that the impact of the outlier cap has been successful in addressing abuse of this provision of the payment system.

Response: We thank commenters for their recognition of the need for the outlier payment limit and recognize the concerns expressed by many to ensure that the 2.5 percent target in outlier payments allowed is expended. We agree on the importance of ensuring access to care for high cost Medicare beneficiaries. We also agree that the outlier cap policy plays an important part in addressing abuse of the payment system. As stated in our proposed rule, we will continue to monitor outlier payments as a percentage of total HH PPS payments as newer data becomes available.

At the writing of this final rule, the most current 2010 claims data shows the outlier payment outlay has increased from 1.68 to 1.91 percent of total 2010 HH expenditures. We recognize that this percentage still falls below the 2.5 percent outlier target. We believe it is necessary to finalize the outlier policy 0.67 FDL ratio and 0.80 loss-sharing ratio as proposed to ensure we do not violate the statutory mandate to not exceed 2.5 percent of expected HH expenditures in outlier payments. We also note that an expected correction to a claims processing error related to the outlier cap may change the final outlier expenditures in CY 2010.

We assure commenters that we intend to thoroughly analyze ways to improve the HH PPS's ability to identify patient severity and cost, address possible home health access issues for high cost patients, and investigate options for improving the HH PPS outlier policies as part of the home health study.

Comment: A number of commenters specifically suggested that the cost sharing ratio of 0.80 be increased rather than lowering the FDL and that CMS should move away from using the low utilization payment adjustment (LUPA) as the proxy for actual cost in computing the outlier payment, believing that actual agency-specific costs subject to a cap or a per visit outlier cap would further reduce outlier abuse and better compensate agencies that use the outlier provision judiciously. Many commenters expressed their belief that outlier payments should play an important part in addressing the needs of patients whose extraordinary costs are beyond the compensation offered by regular HH PPS payments. One of the commenters stated that CMS continues to focus on the outlier payment boost as if it were a profit-making tool for HHAs even though most outlier episodes lose money. Another commenter requested in particular that CMS exempt special needs certified HHAs that serve high-cost patients with multiple clinical issues from the 10 percent outlier cap threshold. One such commenter added that CMS should further evaluate the outlier threshold in relationship to non-routine supplies (NRS) due to this commenter's concern that patients with complex wounds might be adversely impacted.

Response: We reiterate that we intend to analyze alternatives to our current outlier policy as part of the home health study mandated by section 3131 of the Affordable Care Act. The study calls for CMS to investigate improvements to the HH PPS to account for patients with varying severity of illness. We agree with commenters that the current HH PPS outlier payments play an important role in addressing the needs of patients whose costs are beyond the compensation offered by regular HH PPS payments. Regarding possible exemptions for special needs certified HHAs that serve high-cost patients with multiple clinical issues from the 10 percent outlier cap threshold, we note that 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 statutory authority to exempt any providers from the 10 percent outlier cap. Lastly, we will also include the commenter's suggested NRS analysis as part of the Affordable Care Act-mandated home health access study.

In summary, as described above, preliminary analysis of partial 2010 claims described in the proposed rule indicated outlier payments to be approximately 1.68 percent of total HH PPS payments. For this final rule, we have updated our analysis with a full year of CY 2010 data. The data show the outlier payment percentage has increased to 1.91 percent of total HH PPS payments.

TABLE 12: Outlier Payment History (CY 2004 through CY 2010)

Year	Outlier Payment	Total HH PPS Payment	Outlier Payment Percentage
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%
2009	$1,204,246,569	$18,895,476,901	6.37%
2010	$369,659,900	$19,346,889,521	1.91%

In addition, there exists a claims processing issue/problem that upon being corrected, could change the final outlier expenditures in CY 2010.

To ensure that we adhere to our statutory mandate to expend no more than 2.5 percent of expected total HH PPS payments in outlier payments, we are maintaining our current policies of a FDL ratio of 0.67 and a loss-sharing ratio of 0.80 for CY 2012. Table 18 from our proposed rule has been updated and shows the outlier payment history as a percentage of total HH PPS payments between Calendar Years 2004 and 2010.

D. CY 2012 Rate Update

1. Home Health Market Basket Update

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

and may result in payment rates under the system under this subsection for a year being less than such payment rates for the preceding year.''

In the proposed rule, we proposed a home health (HH) market basket update of 2.5 percent for CY 2012. This update was based on IHS Global Insight Inc.'s first quarter 2011 forecast, utilizing historical data through the fourth quarter of 2010. Since publication of the proposed rule, we have a revised HH market basket update of 2.4 percent based on IHS Global Insight Inc.'s third quarter 2011 forecast, utilizing historical data through the second quarter of 2011. A detailed description of how we derive the HH market basket is available in the CY 2008 HH PPS proposed rule (72 FR 25356, 25435). Due to the requirement in section 1895(b)(3)(B)(vi) of the Act, the CY 2012 HH PPS payment update percentage is to be calculated by reducing the CY 2012 HH market basket update of 2.4 percent by 1 percentage point. In effect, the final CY 2012 HH PPS payment update percentage is calculated to be 1.4 percent.

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

Comment: One commenter objected to CMS decreasing the market basket increase.

Response: Section 3401(e) of the Affordable Care Act mandates the 1 percentage point decrease to the home health market basket update.

Comment: One commenter criticized the market basket index, claiming that it fails to include consideration of the direct cost increases that CMS rules may have on the delivery of care. Instead, it evaluates general cost changes such as the cost of caregivers, transportation, insurance, and office space.

The commenter further stated that this approach does not provide CMS with the information needed to adjust payment rates in relation to regulatory cost increases. When the home health services ''product'' changes because of new regulatory or administrative requirements, CMS must include an element in the market basket index to address the resulting cost changes. Or alternatively, they request CMS adjust base payment rates to account for such cost, as it has done in the past for costs such as OASIS.

Finally, the commenter claims the weaknesses in the current market basket index calculation method is highlighted this year in the significant difference between the index rate applied to hospitals and the index rate proposed for HHAs. A difference of 0.5 is, on its face, unsupportable, as HHAs have experienced significantly increased administrative costs for the face-to-face encounter rule and the requirements to greatly increase professional therapist assessments of patients along with increases in gas costs for a provider group that travels nearly 5 billion miles a year.

Response: The home health market basket is a fixed-weight Laspeyres-type price index. The index is not, nor is it intended to be, a cost index. Its weights reflect the cost distribution for a selected base year while current-period price changes are measured. As such, the index measures ''pure'' price changes only. The effects on total expenditures resulting from periodic changes in the quantity or mix of goods and services purchased by home health providers are, by design, captured in the base year weights (or cost shares), which are updated on a recurring basis.

The 0.5 percentage point difference referenced by the commenter (3.0 percent final FY 2012 IPPS market basket update minus the 2.5 percent proposed CY 2012 HH market basket update [not the 2.4 percent final CY 2012 HH market basket update]) between the HHA market basket increase and IPPS market basket increase is the result of the differences in the inputs that HHAs and IPPS hospitals purchase to provide medical care services and the expected price changes associated with those inputs. For instance, IPPS hospitals tend to employ a staff with a higher skill mix (with the price growth associated with that skill mix tending to grow slightly more rapidly). Likewise, a significant share of hospital costs is dedicated to prescription drug expenses (a category that is projected to experience relatively higher price growth in the coming year).

2. Home Health Care Quality Reporting Program

a. Background and Quality Reporting Requirements

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

b. OASIS Data

Accordingly, for CY 2012, we proposed to continue to use a HHA's submission of OASIS data as one form of quality data to meet the requirement that the HHA submit data appropriate for the measurement of health care quality. We proposed for CY 2012 to consider OASIS assessments submitted by HHAs to CMS in compliance with HHA Conditions of Participation and Conditions for Payment for episodes beginning on or after July 1, 2010 and before July 1, 2011 as fulfilling one portion of the quality reporting requirement for CY 2012. This time period would allow 12 full months of data collection and would provide us the time necessary to analyze and make any necessary payment adjustments to the payment rates for CY 2012. We proposed to reconcile the OASIS submissions with claims data to verify full compliance with the OASIS portion of the quality reporting requirements in CY 2012 and each year thereafter on an annual cycle July 1 through June 30 as described above.

As set forth in the CY 2008 final rule, agencies do not need to submit OASIS data for those patients who are excluded from the OASIS submission requirements under the Home Health Conditions of Participation (CoPs) § 484.1–§ 484.265, as well as those excluded, as described at 70 FR 76202:

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

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), agencies that become Medicare-certified on or after May 1 of the preceding year (2011 for payments in 2012) are excluded from any payment penalty for quality reporting purposes for the following CY. Therefore, HHAs that are certified on or after May 1, 2011 are excluded from the quality reporting requirement for CY

2012 payments. These exclusions only affect quality reporting requirements and do not affect the HHA's reporting responsibilities under the Conditions of Participation and Conditions of Payment.

(1) OASIS Data and Annual Payment Update

HHAs that submit OASIS data as specified above are considered to have met one portion of the quality data reporting requirements. Additional portions of the quality data reporting requirements are discussed below under sections D.2.c and D.2.d.

(2) OASIS Data and Public Reporting

Section 1895(b)(3)(B)(v)(III) of the Act further states that ''[t]he Secretary shall establish procedures for making data submitted under sub clause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.''

To meet the requirement for making such data public, we proposed to continue using a subset of OASIS data that is utilized for quality measure development and reported on the Home Health Compare Web site. Currently, the Home Health Compare Web site lists 23 quality measures from the OASIS data set as described below. The Home Health Compare Web site, which was redesigned in October 2010, is located at *http://www.medicare.gov/HHCompare/Home.asp*. Each HHA currently has pre-publication access, through the CMS contractor, to its own quality data that the contractor updates periodically. We proposed to continue this process, to enable each agency to view its quality measures before public posting of data on Home Health Compare.

The following 13 OASIS–C process measures have been publicly reported on Home Health Compare since October 2010:

- Timely initiation of care.
- Influenza immunization received for current flu season.
- Pneumococcal polysaccharide vaccine ever received.
- Heart failure symptoms addressed during short-term episodes.
- Diabetic foot care and patient education implemented during short-term episodes of care.
- Pain assessment conducted.
- Pain interventions implemented during short-term episodes.
- Depression assessment conducted.
- Drug education on all medications provided to patient/caregiver during short-term episodes.
- Falls risk assessment for patients 65 and older.
- Pressure ulcer prevention plans implemented.
- Pressure ulcer risk assessment conducted.
- Pressure ulcer prevention included in the plan of care.

We published information about these new process measures in the **Federal Register** in the CY 2010 HH PPS proposed and final rules (74 FR 40960 and 74 FR 58096, respectively), and in the CY 2011 HH PPS proposed and final rules (75 FR 43250 and 75 FR 70401, respectively). We proposed and finalized the decision to update Home Health Compare in October 2010 to reflect the addition of the process measures.

We proposed to continue publicly reporting these 13 process measures and consider them as measures of home health quality.HERE

The following 10 OASIS–C outcome measures are currently listed on Home Health Compare:

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

As proposed and finalized in the CY 2011 HH PPS final rule (75 FR 70401), these OASIS–C outcome measure calculations were publicly reported for the first time in July 2011.

(3) Transition From OASIS–B1 to OASIS–C

The implementation of OASIS–C on January 1, 2010 impacted the schedule of quality measure reporting for CY 2010 and CY 2011. Although sufficient OASIS–C data were collected during CY 2010 and early CY 2011 and risk models were in development, the outcome reports (found on Home Health Compare and the contractor outcome reports used for HHA's performance improvement activities) remained static with OASIS–B1 data. The last available OASIS–B1 reports remained in the system and on the Home Health Compare site until they could be replaced with OASIS–C reports. Sufficient numbers of patient episodes were needed to report measures based on new OASIS–C data. This is important because measures based on patient sample sizes taken over short periods of time can be inaccurate and misleading due to issues like seasonal variation and under-representation of long-stay home health patients. Once sufficient OASIS–C data were collected and submitted to CMS's national repository, we could begin producing new reports based on OASIS–C.

December 2009 was the last month for which outcome data were calculated for OASIS–B1 data and OASIS–B1 CASPER outcome reports continued to be available after March 2010. OASIS–C process measures were made available to preview in September 2010 and were publicly reported in October 2010. OASIS–C outcome measures were made available to preview in June 2011 and were publicly reported in July 2011.

c. Claims Data, Requirements, and Outcome Measure Change

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

The change to OASIS–C brought about modifications to the OASIS–B1 measure ''Emergent Care,'' and resulted in the following change to that measure:

- *Emergency Department Use without Hospitalization:* This measure replaces the previously reported measure: Emergent care. It excludes emergency department visits that result in a hospital admission because those visits are already captured in the acute care hospitalization measure.

Upon review of actual claims data for emergency department visits and responses to OASIS–C data item M2300, we determined that the claims data are a more robust source of data for this measure, therefore the OASIS-based measure ''Emergency Department (ED) Use Without Hospitalization'' was not publicly reported effective July 2011. The ED Use Without Hospitalization measure will be recalculated from claims data and we proposed that public reporting of the claims-based measure would begin January 2012. We invited comment on the proposed use of claims data in the calculation of home health quality measures and as an additional measurement of home health quality.

To summarize, we proposed that the following 13 process and 9 outcome measures, which comprise measurement of home health care quality, would continue to be publicly reported in July 2011 and quarterly thereafter:

- Timely initiation of care.
- Influenza immunization received for current flu season.
- Pneumococcal polysaccharide vaccine ever received.
- Heart failure symptoms addressed during short-term episodes.
- Diabetic foot care and patient education implemented during short-term episodes of care.
- Pain assessment conducted,
- Pain interventions implemented during short-term episodes.
- Depression assessment conducted.
- Drug education on all medications provided to patient/caregiver during short-term episodes.
- Falls risk assessment for patients 65 and older.
- Pressure ulcer prevention plans implemented.
- Pressure ulcer risk assessment conducted.
- Pressure ulcer prevention included in the plan of care.
- Improvement in ambulation/locomotion.
- Improvement in bathing.
- Improvement in bed transferring.
- Improvement in management of oral medications.
- Improvement in pain interfering with activity.
- Acute care hospitalization.
- Improvement in dyspnea.
- Improvement in status of surgical wounds.
- Increase in number of pressure ulcers.

We proposed that the claims-based measure ''Emergency Department Use without Hospitalization'' would be publicly reported in January 2012.

Increase in Number of Pressure Ulcers Measure

We did not receive any comment related to the Increase in Number of Pressure Ulcers measure. However, as a part of our measure maintenance process which was ongoing at the time of the proposed rule, we determined that the rates for this measure do not distinguish between poor performance and good performance and the risk adjustment model for this measure is insufficient. For these reasons, we will not finalize this measure for public reporting.

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

Comment: We received a total of 11 comments pertaining to the home health quality reporting program, OASIS section. Ten of those comments were supportive of the proposal for continued use of the OASIS based process and outcome measures, as well as the use of claims based data when claims data are applicable and not burdensome to collect. The Emergency Department Use without Hospitalization and the Acute Care Hospitalization measures were specifically noted by commenters as measures for which claims would be more precise and readily available data sources. One commenter requested further clarification of what data CMS will use to calculate this quality measure (for example, how would observation stays be calculated after a planned procedure and how would the agency monitor the timing of when the last OASIS assessment was completed as compared to when the ER visit occurred?). Addition of a claims-based measure related to observation stays was also suggested.

Response: We appreciate the positive feedback supporting the proposed use of OASIS process and outcome measures and particularly those comments supporting the addition of claims as a data source. In response to the request for further clarification, CMS is still working with the measure developer to determine the precise specifications for the claims-based measure of Emergency Department Use Without Hospitalization. The specific disposition of observation stays is undetermined. Details of the measure specifications will be provided when finalized.

Comment: We received one comment expressing confusion regarding the use of claims data, expressing concern that slow claims filing might potentially impact the accuracy of the ED Use Without Hospitalization measure, noting that using the same data base for all measures makes more sense and stating that the fact that CMS has concerns about the reliability of OASIS data for one measure suggests concern about the reliability of OASIS data overall. This commenter recommends that CMS abandon the proposal to substitute hospital claims data as the source for the ED Use Without Hospitalization measure.

Response: In this response, we intend to clarify the reason for use of claims data for the ED Use Without Hospitalization measure. OASIS item M2300 asks: ''Since the last time OASIS data were collected, has the patient utilized a hospital emergency department?'' OASIS data is not collected on every home health visit, and M2300 is reported only at the time of transfer or discharge. CMS contractors compared responses on OASIS item M2300 to submitted outpatient claims for ER visits for continuously enrolled Medicare fee-for-service beneficiaries who had a home health stay of less than 60 days during 2010. This analysis showed that only 25 percent of outpatient ER visits were correctly reported on item M2300, implying that a measure of emergency department use without hospitalization calculated from M2300 is unreliable. Although there is a delay in receiving outpatient claims, 90 percent of outpatient claims are received within 2 months of service date and thus utilization measures calculated from claims can be reported for the same periods as measures calculated from OASIS data. Additionally, as CMS relies on submitted outpatient claims for payment purposes, these data are already extensively verified.

Using a single database as the source of all measures is not the best approach. It is not feasible to do so because the data collected on ED Use Without Hospitalization via OASIS is not reliable and enhancing the reliability of this data may impose undue burden on providers. The benefits of reliable data outweigh the slight complication of drawing quality data from two sources.

The problem with item M2300 does not necessarily imply there may be problems with other OASIS items. Other OASIS items involve a home health practitioner reporting direct observation of the patient. M2300, however, asks for information that the home health practitioner does not directly observe. The decision to visit the emergency room is typically made by the patient or by the patient's family or other primary care-giver. The HHA's knowledge that an emergency department visit occurred is dependent on the patient or caregiver informing the HHA about the event.

Reliance on Medicare outpatient claims is considerably less burdensome to HHAs than requiring additional investigation of potential emergency department visits. The claims-based measure is still under development and will be thoroughly tested and validated prior to public reporting. As a result of the comments and ongoing evaluation of the proposed measures, we finalize all as we proposed with these exceptions:

- Public reporting of the claims-based ED Use Without Hospitalization measure will begin as early as January 2012, contingent on the measure's readiness for public reporting; and
- The Increase in Number of Pressure Ulcers measure will no longer be publicly reported effective as early as October 2011.

d. Home Health Care CAHPS Survey (HHCAHPS)

In the CY 2011HH PPS final rule Rate Update for (75 FR 70404 *et seq.*), we stated that the expansion of the HH quality measures reporting requirements for Medicare-certified agencies will include the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care (HHCAHPS) Survey for the CY 2012 annual payment update (APU). We are maintaining our existing policy as issued in the CY 2011 HH PPS Rate Update, and moved forward to have HHCAHPS linkage to the pay-for-reporting (P4R) requirements affecting the HH PPS rate update for CY 2012.

(1) Background and Description of HHCAHPS

As part of the U.S. Department of Health and Human Services' (DHHS) Transparency Initiative, we have implemented a process to measure and publicly report patient experiences with home health care using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) CAHPS® program, and endorsed by the National Quality Forum (NQF). The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS (HHCAHPS) survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. Prior to this survey, there was no national standard for collecting information about patient experiences that would enable valid comparisons across all HHAs. The history of the HHCAHPS has been given in previous rules, but it also available on our Web site at *https://homehealthcahps.org* and also, in the *HHCAHPS Protocols and Guidelines Manual,* which is downloadable from our Web site.

For public reporting purposes, we will report five measures—three composite measures and two global ratings of care from the questions on the HHCAHPS survey. The publicly reported data will be adjusted for differences in patient mix across HHAs. We anticipate that HHCAHPS will first be publicly reported in April 2012 on Home Health Compare on *http://www.medicare.gov.* For the HHCAHPS reported measures, each composite measure consists of four or more questions regarding one of the following related topics:

- Patient care (Q9, Q16, Q19, and Q24);
- Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23);
- Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14);

The two global ratings are the overall rating of care given by the HHA's care providers, and the patient's willingness to recommend the HHA to family and friends.

The HHCAHPS survey is currently available in six languages. At the time of the CY 2010 HH PPS final rule, HHCAHPS was only available in English and Spanish. In the proposed rule for CY 2010, we stated that we would provide additional translations of the survey over time in response to suggestions for any additional language translations. We now offer HHCAHPS in English, Spanish, Mandarin (Simplified) Chinese, Cantonese (Classical) Chinese, Russian, and Vietnamese languages. We will continue to consider additional translations of the HHCAHPS in response to the needs of the home health patient population.

All of the requirements about eligibility for HHCAHPS and conversely, which home health patients are ineligible for HHCAHPS are delineated and detailed in the *HHCAHPS Protocols and Guidelines Manual* which is downloadable from the official Home Health Care CAHPS Web site *https://homehealthcahps.org.* To be eligible, home health patients must have received at least two skilled home health visits in the past 2 months, paid for by Medicare or Medicaid. HHCAHPS surveys will *not* be taken from patients who are:

- Under the age of 18;
- Deceased;
- Receiving hospice care;
- Receiving routine maternity care only;
- Living in a State that restricts the release of patient information for a specific condition or illness that the patient has; or are
- Requesting that their names not be released to anyone.

We stated in previous rules that Medicare-certified agencies are required to contract with an approved HHCAHPS survey vendor. Beginning in summer 2009, interested vendors applied to become approved HHCAHPS survey vendors. HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We now have approximately 40 approved HHCAHPS survey vendors. The list of approved vendors is available at *https://homehealthcahps.org.*

(2) HHCAHPS Requirements for CY 2012

In the CY 2010 HH PPS final rule (74 FR 58078 *et seq.*), we stated that HHCAHPS would not be required for the APU for CY 2011. We did this so that HHAs would have more time to prepare for the implementation of HHCAHPS. Therefore, in the CY 2010 HH PPS final rule, we stated that data collection should take place beginning in the third quarter of CY 2010 to meet the HHCAHPS reporting requirements for the CY 2012 APU. In the CY 2010 HH PPS final rule, and in the CY 2011 HH PPS final rule, we stated that Medicare-certified agencies would be required to participate in a dry run for at least 1 month in third quarter of 2010 (July, August, and/or September), and to begin continuous monthly data collection in October 2010 through March 2011, for the CY 2012 APU. The dry run data were due to the Home Health CAHPS® Data Center by 11:59 p.m., Eastern standard time (e.s.t.) on January 21, 2011. The dry run data will not be publicly reported on the CMS Home Health Compare Web site. The purpose of the dry run was to provide an opportunity for vendors and HHAs to acquire first-hand experience with data collection, including sampling and data submission to the Home Health Care CAHPS Data Center.

In the CY 2011 HH PPS final rule, it was stated that the mandatory period of data collection for the CY 2012 APU would include the dry run data in the third quarter 2010 that were due 11:59 p.m., e.s.t., on January 21, 2011, data from each month in the fourth quarter of 2010 (October, November and December 2010), and data from each month in the first quarter 2011 (January, February and March 2011). We previously stated that all Medicare-certified HHAs should continuously collect HHCAHPS survey data for every month in every quarter beginning October 2010, and submit these data for the fourth quarter of 2010 to the Home Health CAHPS Data Center by 11:59 p.m., Eastern Daylight Time (e.d.t.), on April 21, 2011. In the CY 2011 HH PPS final rule, we stated that the data collected for the 3 months of the first quarter 2011 would have to be submitted to the Home Health CAHPS Data Center by 11:59 p.m., e.d.t., on July 21, 2011. We also stated that these data submission deadlines would be firm (that is, no late submissions would be accepted). HHAs must monitor their HHCAHPS survey vendors to ensure that their HHCAHPS data are submitted

on time to the Home Health Care CAHPS Data Center. HHAs can access and review their data submission reports on *https://homehealthcahps.org,* and follow the directions on how to access these reports in their HHA account.

These periods (a dry run in third quarter 2010, and 6 months of data from October 2010 through March 2011) were deliberately chosen to comprise the HHCAHPS reporting requirements for the CY 2012 APU because they coincided with the OASIS-C reporting requirements that would already have been due on June 30, 2011 for the CY 2012 APU. We also exempted Medicare-certified agencies from the HHCAHPS reporting requirements if they had fewer than 60 HHCAHPS-eligible unique patients from April 1, 2009 through March 31, 2010. In the CY 2011 HH PPS final rule, we stated that by January 21, 2011 HHAs would need to provide CMS with patient counts for the period of April 1, 2009 through March 31, 2010. We posted a form on *https://homehealthcahps.org* that the HHAs needed to use to submit their patient counts. This patient counts reporting requirement pertains only to Medicare-certified HHAs with fewer than 60 HHCAHPS eligible, unduplicated or unique patients for that time period. The aforementioned agencies are exempt from conducting the HHCAHPS survey for the APU in CY 2012.

We stated in the CY 2010 HH PPS final rule (74 FR 58078) and in the CY 2011 HH PPS final rule that we would exempt newly Medicare-certified HHAs. If an HHA became Medicare-certified April 1, 2010 and after, then they would be exempt from participating in HHCAHPS.

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

(3) HHCAHPS Reconsiderations and Appeals Process

We stated in the CY 2011 HH PPS final rule that we would propose a reconsiderations and appeals process for HHAs not meeting the HHCAHPS reporting requirements for CY 2012. We are finalizing our proposed reconsiderations and appeals process for HHAs that fail to meet the HHCAHPS data collection requirements. HHAs that are not compliant with OASIS-C and/or HHCAHPS reporting requirements for the CY 2012 APU were notified that they were noncompliant with CY 2012 quality reporting requirements. We issued a Joint Signature Memorandum to RHHIs/MACs with a list of HHAs not compliant with OASIS and/or HHCAHPS (TDL–aa453, 08–26–2011 in a CMS Memorandum dated September 2, 2011). The September Memorandum included language regarding the evidence required for the reconsideration process, how to prepare a request for reconsideration of the CMS decision, and that HHAs will have 30 days to file their requests for reconsiderations to CMS. We will examine each request and make a determination about whether we plan to uphold our original decision. HHAs will receive CMS' reconsideration decision by December 31, 2011. HHAs have a right to appeal under 42 CFR part 405, subpart R, to the Provider Reimbursement Review Board (PRRB) if they were not satisfied with the CMS reconsideration determination.

The CMS Memorandum dated September 2, 2011 included the TDL–11353, and was published in the CMS Manual System, Medicare Claims Processing. The CMS Memorandum was sent to Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers. The RHHIs/MACs verified the claims submissions for the identified timeframe for the 2012 APU period, to confirm that the claims match the HHAs we identified as noncompliant with OASIS and HHCAHPS. The RHHIs/MACs identified and notified the HHAs that they could lose 2 percent of their 2012 APU, and provided them with instructions on how to request reconsideration of their noncompliant status in respect to reporting OASIS and/or HHCAHPS for the CY 2012 APU. If HHAs choose to seek reconsideration of the CMS decision (that they did not fulfill the HHCAHPS reporting requirements), then HHAs are strongly advised to access and review their data submissions reports on *https://homehealthcahps.org* for information regarding their vendors data submission activities for the months comprising the APU period. The RHHIs/MACS will forward the HHAs requests for reconsideration of their noncompliance status for HHCAHPS and/or OASIS reporting requirements to CMS on a flow basis so that CMS can review and prepare recommendations for cross component review. The HHAs would be informed about CMS' final decisions by December 31, 2011.

(4) HHCAHPS Oversight Activities

We stated in the CY 2011 HH PPS final rule that vendors and HHAs are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that HHAs and approved survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.* As stated, all approved survey vendors must develop a Quality Assurance Plan (QAP) for survey administration in accordance with the *HHCAHPS Protocols and Guidelines Manual.* The first QAP must be submitted within 6 weeks of the data submission deadline after the vendor's first quarterly data submission. The HHCAHPS Coordination Team reviews the QAPs and recommends specific revisions. HHCAHPS survey vendors must revise their QAP until it is fully satisfactory to the HHCAHPS Coordination Team. Once the vendor has a fully acceptable QAP, the vendor will submit subsequent updated QAPs to the HHCAHPS Coordination Team on an annual basis thereafter, or update the QAP at any time that changes occur in staff, vendor capabilities, or systems. A model QAP is included in the *HHCAHPS Protocols and Guidelines Manual.* The QAP should include the following:

- Organizational Background and Staff Experience.
- Work Plan.
- Sampling Plan.
- Survey Implementation Plan.
- Data Security, Confidentiality and Privacy Plan.
- Questionnaire Attachments.

As part of the oversight activities, the HHCAHPS Survey Coordination Team conducts on-site visits to the HHCAHPS vendors. The purpose of the site visits is to allow the HHCAHPS Coordination Team to observe the entire Home Health Care CAHPS Survey implementation process, from the sampling stage through file preparation and submission, as well as to assess how the HHCAHPS data are stored. The HHCAHPS Survey Coordination Team reviews the survey vendor's survey systems, and assesses administration protocols based on the *HHCAHPS Protocols and Guidelines Manual* posted at *https://homehealthcahps.org.* The HHCAHPS Survey Coordination Team includes the CMS staff assigned to work on HHCAHPS, and the Federal contractor for the HHCAHPS implementation. HHCAHPS survey vendors are not part of the HHCAHPS Survey Coordination Team. The systems and program review include, but are not limited, to the following:

- Survey management and data systems;
- Printing and mailing materials facilities;

- Telephone call center facilities;
- Data receipt, entry and storage facilities; and
- Written documentation of survey processes.

After the site visits, HHCAHPS survey vendors are given a defined time period in which to correct any identified issues and provide follow-up documentation of corrections for review. In general, the defined time periods will be between 2 weeks to 1 month after these issues are stated in the HHCAHPS Coordination Team's site visit report to the HHCAHPS survey vendor. HHCAHPS survey vendors will be subject to follow-up site visits as needed.

(5) HHCAHPS Requirements for CY 2013

For the CY 2013 APU, HHCAHPS data collection and reporting are required for four continuous quarters. The data collection period includes second quarter 2011 through first quarter 2012. HHCAHPS survey vendors acting on behalf of their contracted HHAs are required to submit HHCAHPS data files quarterly to the Home Health CAHPS Data Center on October 21, 2011, January 23, 2012, April 19, 2012, and July 19, 2012.

For the CY 2013 APU, HHAs will be required to submit their HHCAHPS data files to the Home Health CAHPS Data Center for CY 2013 as follows: The data for the second quarter 2011 by 11:59 p.m., e.d.t., on October 21, 2011; the data for the third quarter 2011 by 11:59 p.m., e.s.t., on January 23, 2012; the data for the fourth quarter 2011 by 11:59 p.m., e.d.t., on April 19, 2012; and the data for the first quarter 2012 by 11:59 p.m., e.d.t., on July 19, 2012. Beginning with April 2012 quarterly data submissions and moving forward, HHCAHPS quarterly data submissions will always be the third Thursday of the month (in the months of April, July, October, and January). HHAs must monitor their HHCAHPS survey vendors to ensure that their HHCAHPS data is submitted on time to the Home Health Care CAHPS Data Center. HHAs can access and review their data submission reports on *https://homehealthcahps.org,* and follow the directions on how to access these reports on their HHA account.

HHAs that have fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2010 through March 31, 2011 are exempt from the HHCAHPS data collection and submission requirements for the CY 2013 APU. For the CY 2013 APU, agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients are required to submit their counts on the Participation Exemption Request form posted at *https://homehealthcahps.org* by 11:59 p.m., e.d.t., on April 19, 2012. This deadline is firm, as are all of the HHCAHPS quarterly data submission deadlines.

HHAs receiving Medicare certification on or after April 1, 2011 are exempt from the HHCAHPS data collection and submission requirements for the CY 2013 APU, because these HHAs were not Medicare-certified in the period of April 1, 2010 and March 31, 2011.

(6) HHCAHPS Codified Criteria

The following criteria from the CY 2011 HH PPS final rule are now revised so that the requirements for OASIS and Home Health CAHPS are clearly distinguishable in the Federal regulations. We are revising this section to clarify that HHCAHPS is associated with the APU described at § 484.225(i) and the quality reporting requirements, and *not* with other payment requirements.

In the CY 2011 HH PPS final rule (75 FR 70465), we stated for § 484.250, Patient Assessment Data, that ''An HHA must submit to CMS the OASIS–C data described at § 484.55(b)(1) and Home Health Care CAHPS data for CMS to administer the payment rate methodologies described in § 484.215, § 484.230, and § 484.235 of this subpart, and meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.''

We are revising this section to clarify that HHCAHPS is only associated with the APU described at § 484.225(i) and the quality reporting requirements, and not with other payment requirements.

(7) HHCAHPS Requirements for CY 2014

For the CY 2014 APU, HHCAHPS data collection and reporting is required for four continuous quarters. The data collection period includes the second quarter 2012 through the first quarter 2013. HHAs are required to submit their HHCAHPS data files to the Home Health CAHPS Data Center the third Thursday of the month for the months of October 2012, January 2013, April 2013 and July 2013. HHAs are required to submit their HHCAHPS data files to the Home Health CAHPS Data Center for CY 2014 as follows: For the second quarter 2012 by 11:59 p.m., e.d.t., on October 18, 2012; for the third quarter 2012 by 11:59 p.m., e.s.t., on January 17, 2013; for the fourth quarter 2012 by 11:59 p.m., e.d.t., on April 18, 2013; and for the first quarter 2013 by 11:59 p.m., e.d.t., on July 18, 2013. HHAs must monitor their HHCAHPS survey vendors to ensure that their HHCAHPS data is submitted on time to the Home Health Care CAHPS Data Center. HHAs can access and review their data submission reports on *https://homehealthcahps.org,* and follow the directions on how to access these reports on their HHA account.

As noted, we exempt HHAs receiving Medicare certification on or after April 1, 2012 from the HHCAHPS data collection and submission requirements for the CY 2014 APU, as data submission and analysis will not be possible for an agency that late in the reporting period for the CY 2014 APU requirements.

As noted, all HHAs that have fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2011 through March 31, 2012 are exempt from the HHCAHPS data collection and submission requirements for the CY 2014 APU. For the CY 2014 APU, agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients are required to submit their counts on the Participation Exemption Request form posted on *https://homehealthcahps.org* by 11:59 p.m., e.d.t., on April 18, 2013. This deadline is firm, as are all of the HHCAHPS quarterly data submission deadlines.

(8) For Further Information on the HHCAHPS Survey

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

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

Comment: We received several comments about the proposed reconsiderations and appeals process. We were urged not to have the process be burdensome to HHAs.

Response: We agree that the process should not be burdensome to HHAs. We have modeled the HHCAHPS reconsiderations and appeals process after the one that is used for Hospital CAHPS, which has been in use for 6 years. We have described the HHCAHPS requirements in the notification memo that the RHHIs/MACs will be sending to the affected HHAs, on behalf of CMS. We believe that the HHAs will have enough time to prepare their reconsideration appeal to CMS within

30 days. CMS will fully examine every reconsideration request.

Comment: We received comments that there are several variables that may result in the collection of inaccurate HHCAHPS data that are beyond the control of the HHA such as patient confusion on how to complete the survey or patient refusal to complete the survey.

Response: We allow proxies to complete the HHCAHPS survey for home health patients who are unable to complete the survey on their own. Patient refusal to complete the survey does not result in the collection of inaccurate HHCAHPS data.

As long as the HHCAHPS protocols are followed, HHAs will not be penalized. To meet the APU requirements, HHAs must follow the survey protocols, which allow for non-response and proxy response.

Comment: We received comments that recommended that the results of the HHCAHPS vendor oversight activities be made available to HHAs so they can make informed decisions when selecting or changing their HHCAHPS vendors.

Response: If a vendor has significant issues that would put HHAs at risk for not meeting the APU requirements, CMS will immediately alert the affected HHAs, thereby providing agencies with sufficient time to switch vendors and to ensure that the HHAs will not be penalized if their data collection activities are interrupted because of circumstances outside of their control. We would also note this next to the vendor name on the vendor list that is posted on *https://homehealthcahps.org.* If we find that a vendor does not comply with HHCAHPS protocols and guidelines, or correct in a timely manner any deficiencies that are found during oversight activities, then we will remove that vendor from the approved list.

Comment: We received comments that recommended that CMS explicitly hold HHAs harmless for any failures of HHCAHPS vendors to comply with HHCAHPS protocols and guidelines.

Response: We believe that HHAs must monitor their vendors to ensure that vendors submit data on time, by using the information that is available to them on the HHCAHPS Data Submission Reports. This will also ensure that data is submitted in the proper format, and will subsequently be successfully submitted to the HHCAHPS Data Center.

Comment: We received comments that recommended that CMS provide clear instructions to HHAs on when and what information is appropriate for the HHA to share with its patients regarding the HHCAHPS survey. While we are aware that some of this information has been provided by HHCAHPS contractors, there is still some confusion among providers, and therefore, we believe that additional guidance from the Agency is warranted.

Response: HHAs can say to clients that they may receive an HHCAHPS survey and that it is a legitimate survey that is implemented and sponsored by the Federal government. However, the HHAs should not give information that would coach the patients as to how to complete the HHCAHPS survey. Also, we are assuming that when the commenters wrote that ''we are aware that some of this information has been provided by HHCAHPS contractors'' that they were referring to the HHCAHPS survey vendors, which are not CMS contractors.

Comment: We received comments of concern that the HHCAHPS data may be more subjective impressions of interpersonal relationships with staff than valid measures of clinical and administrative excellence. We would urge CMS to work more closely with the members of the home health community like us as the data begins to be compiled prior to public reporting to prevent possible misunderstanding of these measures by the public.

Response: The HHCAHPS is not supposed to measure the aspects of clinical care that can be captured through a medical record. HHCAHPS focuses on areas where the patient is the best or only source for the information. We believe that the HHCAHPS is a valid measure of patient's perspectives of home health care. The developmental work on the Home Health Care CAHPS began in mid-2006, and the first survey was field-tested (to validate the length and content of the survey) in 2008 by the AHRQ and the CAHPS grantees, and the final survey was used in a national randomized mode experiment in 2009 through 2010.

A rigorous, scientific process was used in the development of the survey, including: A public Call for Measures; literature reviews; focus groups with HH patients; cognitive interviews (several rounds in 2007) with HH patients; extensive stakeholder input; technical expert panel reviews in each phase of the developmental work; comprehensive assessment review and subsequent endorsement in March 2009 by the National Quality Forum. The NQF represents the consensus of many health care providers, consumer groups, professional associations, purchasers, Federal agencies and research and quality organizations); and public responses to **Federal Register** notices. The survey received OMB clearance in July 2009. Key stakeholders and home health experts have been regularly providing feedback to CMS about the draft HHCAHPS data displays and draft information that is being prepared for the display of HHCAHPS data that is being reported on Home Health Compare on *http://www.medicare.gov* in April 2012 and forward.

Comment: We received comments that support the implementation of HHCAHPS because it will meaningfully reduce the incidence of improper home health service use and it will complement the changes approved by the Congress.

Response: We appreciate supportive comments about HHCAHPS. The survey will provide an opportunity for patients to share their perspective about the care provided, and will complement the changes approved by the Congress to expand the quality measures and to increase transparency in home health.

Comment: We received a comment that urged CMS to involve HHA representatives in the analysis of CAHPS to determine which measures are most appropriate for public reporting before posting them on Medicare Compare.

Response: We are following the precedence of other CAHPS surveys that publicly report the data concerning health care providers. We tested and analyzed the individual questions and how they are best grouped together in the formative and developmental stages of the survey that included a national field test. The Technical Expert Panel and the public stakeholders for the Home Health Care CAHPS survey chose these measures after they reviewed the findings of the research grantees that tested the CAHPS survey in the field on behalf of the Federal government. The three composite measures and the two global overall ratings were chosen to best inform the public about the HHCAHPS results for national comparisons.

Comment: We received a comment that the HHA should receive an administrative reimbursement to cover the costs of implementing HHCAHPS.

Response: The collection of the patient's perspectives of care quality data for similar CAHPS surveys, such as the Hospital CAHPS survey, follow the same model where in the health care providers pay the approved survey vendors for the data collection costs and we pay for the training, technical assistance, oversight of vendors and data analysis costs. HHAs are strongly encouraged to report their respective HHCAHPS costs on their CRs but should note that these costs are not

reimbursable under the HH PPS. It is advised that HHAs ''shop around'' for the best cost value for them before contracting with an approved HHCAHPS vendor to conduct the survey on their behalf. The HHCAHP approved survey vendors list is on *https://homehealthcahps.org.*

In summary, we are finalizing the HHCAHPS requirements for the CY 2012 APU as proposed in the CY 2012 HH PPS proposed rule (76 FR 41051). There are no policy changes in HHCAHPS from the proposed rule to the final rule regarding HHCAHPS. The same requirements and deadlines stand as final. The HHCAHPS data submission due date for the CY 2012 APU are in the CY 2011 HH PPS final rule, and they mirror the dates that we stated in this CY 2012 HH PPS final rule. All data submission deadlines for HHCAHPS are posted on the official Web site for HHCAHPS, *https://homehealthcahps.org.*

The periods of a dry run in the third quarter 2010, and monthly data collection beginning in October 2010 through March 2011, comprise the HHCAHPS reporting requirements for the CY 2012 APU. HHAs with patient counts of 59 or fewer patients for the period of April 1, 2009 through March 31, 2010 are exempt from the HHCAHPS reporting requirements for the CY 2012 APU. HHAs that became Medicare-certified on April 1, 2010 or later are exempt from the HHCAHPS reporting requirements for the CY 2012 APU. Continuous monthly data collection is required for HHCAHPS, as the data collection period of April 2011 through March 2012, comprise the data collection months for the CY 2013 APU, and the data collection period of April 2012 through March 2013, comprise the data collection months for the CY 2014 APU.

3. Home Health Wage Index

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

In the November 9, 2005 final rule for CY 2006 (70 FR 68132), we began adopting revised labor market area definitions as discussed in the Office of Management and Budget (OMB) Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of Micropolitan Statistical Areas and Core-Based Statistical Areas (CBSAs). The bulletin is available online at *http://www.whitehouse.gov/omb/bulletins/b03–04.html.* In addition, OMB published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. This rule incorporates the CBSA changes published in the most recent OMB bulletin. The OMB bulletins are available at *http://www.whitehouse.gov/omb/bulletins/index.html.*

Finally, we continue to use the methodology discussed in the CY 2007 HH PPS final rule for (71 FR 65884) to address those geographic areas in which there are no Inpatient Prospective Payment System (IPPS) hospitals and, thus, no hospital wage data on which to base the calculation of the HH PPS wage index. For rural areas that do not have IPPS hospitals and, therefore, lack hospital wage data on which to base a wage index, we use the average wage index from all contiguous CBSAs as a reasonable proxy. Since CY 2007, this methodology has been used to calculate the wage index for rural Massachusetts. However, as indicated in the CY 2012 HH PPS proposed rule (76 FR 41019), there is now a rural IPPS hospital with wage data upon which to base a wage index for rural Massachusetts. Therefore, it is not necessary to apply this methodology to rural Massachusetts for CY 2012.

For rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005).

For urban areas without IPPS hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. At the time of the proposed rule, both CBSA 49700, Yuba City, CA, and CBSA 25980, Hinesville-Fort Stewart, GA, did not have IPPS hospital wage data. However, for this final rule, Yuba City, CA now has IPPS hospital wage data. Therefore, the only urban area without IPPS hospital wage data is Hinesville-Fort Stewart, Georgia (CBSA 25980).

The wage index values are available on the CMS Web site at *http://www.cms.gov/HomeHealthPPS/HHPPSRN/list.asp.*

The following is summary of the comments we received regarding the home health wage index proposal.

Comment: A commenter stated that the current method of adjusting labor costs using the hospital wage index does not accurately account for increased travel costs and lost productivity for time spent traveling to provide services in less densely populated/rural areas. The commenter believes that, pending development of an industry specific wage index, CMS should fully investigate the impact of population density on HHAs costs and efficiency. The commenter suggested that CMS add a population density factor by zip code during calculation of the labor portion of the payment to account for increased costs of providing services in less densely populated areas. This would provide an incentive to providers to serve patients in rural areas while at the same time reducing excess reimbursement for services provided in densely populated urban and congregate living facilities. The net result of the adjustment should be budget neutral or perhaps even result in a cost savings.

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

Comment: One commenter disagreed with the CMS decision to switch from MSAs to CBSAs for the wage index calculation because it had a negative

financial impact on the commenter's geographic area. The commenter notes that more than half of the CBSAs in his State will experience a decrease in CY 2012.

Response: We continue to believe that using OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of determining wage index values.

Comment: Several commenters expressed concerns about inequities in how the wage index is calculated and implemented for HHAs as compared to hospitals within the same CBSA. The wage index for HHA's is based on pre-floor, pre-reclassified hospital wage data, but hospitals in the same geographic area have the ability to apply for reclassification and may be eligible for a rural floor wage index. The commenters state that this inequity has created a competitive advantage for hospitals in recruiting and retaining increasingly scarce nurses and therapists. Any wage index deviations available to hospitals should be equally available to other types of providers.

Response: The regulations that govern the HH PPS currently do not provide a mechanism for allowing providers to seek geographic reclassification. As we have explained in past rulemaking (most recently, in the CY 2011 HH PPS final rule (75 FR 70411)), the rural floor and geographic reclassification in the IPPS are statutorily authorized and are only applicable to hospital payments. The rural floor provision is provided at section 4410 of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) and is exclusive to hospitals. The reclassification provision provided at section 1886(d)(10) of the Act is also specific to hospitals.

Comment: One commenter stated that the hospitals in his area are CAHs and are cost reimbursed. The commenter stated that HHAs cannot offer competitive wages for caregivers who are paid higher and receive better benefits from CAHS in their same service area.

Response: Section 1895(b)(4)(C) of the Act states that the wage adjustment factors used under the HH PPS may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act. Accordingly, we continue to believe that the pre-floor/pre-reclassified hospice wage index continues to be the appropriate wage index used by the HH PPS.

Comment: Several commenters recommended that CMS overhaul the entire wage index system, as recommended by MedPAC in its comments to CMS regarding the hospital wage index, to eliminate such inequities in the future. The commenters requested CMS to put a freeze on any wage index decreases. One commenter believes that the Affordable Care Act gives CMS the authority needed to issue the appropriate changes. However, the commenter did not support the institution of a new index model except when it applies in all provider sectors with whatever distinctions are appropriate to a provider's employment mix. Another commenter believes that the use of the hospital wage index to adjust non-hospital reimbursement rates was originally intended to be an interim measure while CMS examined industry-specific wage data for post-acute services.

Response: As several commenters noted, we have research currently under way to examine alternatives to the wage index methodology, including the issues the commenters mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and provides for a single wage index policy. Section 3137 of the Affordable Care Act provides that the Secretary of Health and Human Services shall submit a report to the Congress by December 31, 2011, that includes a plan to reform the hospital wage index system. Section 3137 of the Affordable Care Act further instructs the Secretary to take into account MedPAC's recommendations on the Medicare wage index classification system, and to include one or more proposals to revise the wage index adjustment applied under section 1886(d)(3)(E) of the Act for purposes of the IPPS. The proposal(s) are to consider each of the following:

- The use of Bureau of Labor Statistics data or other data or methodologies to calculate relative wages for each geographic area.
- Minimizing variations in wage index adjustments between and within MSAs and statewide rural areas.
- Methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality.
- The effect that the implementation of the proposal would have on health care providers in each region of the country.
- Issues relating to occupational mix, such as staffing practices and any evidence on quality of care and patient safety, including any recommendations for alternative calculations to the occupational mix.
- Provide for a transition.

To assist us in meeting the requirements of section 106(b)(2) of the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432, enacted on December 20, 2006) (TRHCA), in February 2008, we awarded a Task Order under our Expedited Research and Demonstration Contract to Acumen, LLC. Acumen, LLC conducted a study of both the current methodology used to construct the Medicare wage index and the recommendations reported to the Congress by MedPAC. Parts 1 and 2 of Acumen's final report, which analyzes the strengths and weaknesses of the data sources used to construct the CMS and MedPAC indexes, is available online at *http://www.acumenllc.com/reports/cms.*

MedPAC's recommendations were presented in the FY 2009 IPPS final rule (available online at *http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf*). We plan to monitor these efforts closely, and to determine what impact or influence they may have on the HH PPS wage index. At this time, we will continue to use the wage index policies and methodologies described in this final rule to adjust the HH PPS rates for differences in area wage levels. However, we will continue to monitor MedPAC and Acumen's progress on any revisions to the IPPS wage index to identify any policy changes that may be appropriate for HHAs and potential changes may be presented in a future proposed rule. The latest information on hospital wage index reform is discussed in the ''Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates'' proposed rule, published in the May 5, 2011 **Federal Register** (76 FR 25788).

Comment: Another commenter objects to the use of the pre-floor, pre-reclassified wage index for home health due to the inaccuracy of using a mix of hospital costs to measure home health labor costs. Problems with the errors and omissions in the hospital cost reporting method are well documented.

Response: We utilize efficient means to ensure and review the accuracy of the hospital CR data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified hospital wage index which is calculated based on CR data from hospitals paid under the hospital IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare CRs. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our intermediaries perform desk reviews on all hospitals'

Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. Furthermore, HHAs have the opportunity to submit comments on the hospital wage index data during the annual IPPS rulemaking period. Therefore, we believe our review processes result in an accurate reflection of the applicable hospital wages for the areas given. We also believe the use of this hospital wage data results in an appropriate adjustment to the labor portion of the home health costs, as required by statute.

Comment: A commenter stated that CMS exacerbates HH wage index disparities by changing the methodology used to address geographic areas in which there are no IPPS hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. For rural areas that do not have IPPS hospitals, CMS used the average wage index from all contiguous CBSAs as a reasonable estimate. This methodology was used to calculate the wage index for only one state, Massachusetts. It is well documented that two CAHs in Massachusetts converted back from CAH status even though doing so would not benefit them directly. By giving up their cost based reimbursement, these two hospitals increase the home health wage index in Massachusetts. Due to the budget neutral nature of this methodology, the HHAs in the other 49 states will face a reduction in payments. The commenter requested that CMS re-evaluate the methodology used to calculate the wage index for rural areas that do not have IPPS hospitals such as was the case for the State of Massachusetts. The inequitable distribution of Medicare payments due to obvious manipulation by specific providers clearly represents preferential treatment.

Response: By nature, the hospital wage index is constructed, in the aggregate, to average to 1.0. Therefore, the index is designed to be budget neutral in the sense that for areas where wage index values increase, those increases are offset by decreases in other areas. The hospital wage index is based on hospital cost data and hospital utilization, and thus, in the aggregate, when applied to HH utilization for the purposes of impacts, the average wage index value may not result to be exactly 1.0. For instance, as explained in the impact analysis section for this final rule, the new wage index will result in an estimated increase of $10 million in aggregate payments to HHAs in CY 2012.

When there is an IPPS hospital in an area, we use the IPPS hospital(s) wage data to calculate the pre-floor, pre-reclassified hospital wage index which is used for the HH PPS wage index. In the CY 2007 HH PPS final rule (71 FR 65905), we established a policy to address rural areas without an IPPS hospital. We use the average wage index from CBSAs which are contiguous to the rural area as an acceptable proxy for a rural wage index. Other post acute payment systems such as SNF and IRF adopted this policy as well. When an IPPS hospital emerges in an area that previously had none, our policy requires that we use the CR data from that hospital to compute that areas wage index.

Comment: Beginning in FY 2004, excluding CAH data from the calculation of the hospital wage index affects the calculation of the HH Wage index. As CAHs are located in rural areas, the absence of CAH wage data further compromises the accuracy, and therefore, appropriateness, of using a hospital wage index to determine the labor costs of HHAs located in rural areas.

Response: As stated above, beginning with the CY 2007 HH PPS final rule (71 FR 65905), we established a policy to address rural areas without an IPPS hospital. In that rule, we addressed commenters concerns with our former policy of using the last available rural wage index for those areas which no longer had an IPPS hospital. We outlined four alternatives for imputing a wage index for those rural areas. We believe that using the average wage index from CBSAs which are contiguous to the rural area as an acceptable proxy for a rural wage index is accurate and appropriate.

Comment: One commenter noted that the wage index is subject to swings in area values that are far beyond manageable by providers. With a wage index reduction of over 10 points in some cases, it is impossible to sensibly budget a fiscal year, particularly when the index is not published until a few months before a calendar year. The commenter suggested that CMS apply limits on the decreases and increases that can occur from one year to the next with the wage index.

Response: Updating the wage index must be done in a budget neutral manner. Establishing limits on how much a particular wage index could increase or decrease from one year to another would not be consistent with budget neutrality. Consequently, we implement updated versions of the wage index, in their entirety.

Comment: A commenter is concerned that the wage index in his locale was proposed to decrease by 4.54 percent from CY 2011 to CY 2012.

Response: The wage index values are based on hospital cost data. Consequently, increases and decreases in the wage index values are normal.

4. CY 2012 Annual Payment Update

a. National Standardized 60-Day Episode Rate

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

In the CY 2008 HH PPS final rule with comment period, we refined the case-mix methodology and also rebased and revised the home health market basket. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage difference, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate is 77.082 percent and the non-labor-related share is 22.918 percent. The CY 2012 HH PPS rates use the same case-mix methodology and application of the wage index adjustment to the labor portion of the HH PPS rates as set forth in the CY 2008 HH PPS final rule with comment period. Following are the steps we take to compute the case-mix and wage adjusted 60-day episode rate:

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

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

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

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

In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. The HH PPS regulations at § 484.225 set forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national

prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

For CY 2012, we proposed to base the wage index adjustment to the labor portion of the HH PPS rates on the most recent pre-floor and pre-reclassified hospital wage index. As discussed in the July 3, 2000 HH PPS final rule, for episodes with four or fewer visits, Medicare pays the national per-visit amount by discipline, referred to as a LUPA. We update the national per-visit rates by discipline annually by the applicable home health market basket percentage. We adjust the national per-visit rate by the appropriate wage index based on the site of service for the beneficiary, as set forth in § 484.230. We proposed to adjust the labor portion of the updated national per-visit rates used to calculate LUPAs by the most recent pre-floor and pre-reclassified hospital wage index. We also proposed to update the LUPA add-on payment amount and the NRS conversion factor by the applicable home health market basket update of 1.4 percent for CY 2012.

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

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

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

HH PPS payment rates are updated, annually, by the HH PPS payment update percentage. For CY 2012, the HH PPS payment update percentage is the CY 2012 home health market basket update percentage (2.4 percent) minus 1 percentage point (per the Affordable Care Act) for a CY 2012 HH PPS payment update percentage of 1.4 percent. For HHAs that do not submit the required quality data, the CY 2012 HH PPS payment update percentage (1.4 percent) is reduced by 2 percentage points for a CY 2012 HH PPS payment update percentage (for HHAs that do not submit the required quality data) of −0.6 percent.

b. Updated CY 2012 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2012 national standardized 60-day episode payment rates, we first look at the CY 2011 rates as a starting point. The CY 2011 national standardized 60-day episode payment rate is $2,192.07. Next, we update that payment amount by the CY 2012 HH PPS payment update percentage of 1.4 percent.

As previously discussed in section II.A. of this final rule (''Case-Mix Measurement''), our updated analysis of the change in case-mix that is not due to an underlying change in patient health status reveals an additional increase in nominal change in case-mix. Therefore, we reduce rates by 3.79 percent in CY 2012, resulting in an updated CY 2012 national standardized 60-day episode payment rate of $2,138.52. The updated CY 2012 national standardized 60-day episode payment rate for an HHA that submits the required quality data is shown in Table 13. The updated CY 2012 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2012 HH PPS payment update percentage (1.4 percent) minus 2 percentage points and is shown in Table 14.

BILLING CODE 4120–01–P

TABLE 13: National 60-Day Episode Payment Amount Updated by the CY 2012 HH PPS Payment Update Percentage, Before Case-Mix Adjustment and Wage Adjustment Based on the Site of Service for the Beneficiary

CY 2011 National Standardized 60-Day Episode Payment Rate	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent	Reduce by 3.79 percent for nominal change in case-mix	CY 2012 National Standardized 60-Day Episode Payment Rate.
$2,192.07	x 1.014	x 0.9621	$2,138.52

TABLE 14: For HHAs that Do Not Submit the Quality Data –National 60-Day Episode Payment Amount Updated by the CY 2012 HH PPS Payment Update Percentage (minus 2 percentage points) Before Case-Mix Adjustment and Wage Adjustment Based on the Site of Service for the Beneficiary

CY 2011 National Standardized 60-Day Episode Payment Rate	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent minus 2 percentage points (-0.6 percent)	Reduce by 3.79 percent for nominal change in case-mix	CY 2012 National Standardized 60-Day Episode Payment Rate.
$2,192.07	x 0.994	x 0.9621	$2096.34

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

In calculating the CY 2012 national per-visit rates used to calculate payments for LUPA episodes and to compute the imputed costs in outlier calculations, the CY 2011 national per-visit rates for each discipline are updated by the CY 2012 HH PPS payment update percentage of 1.4 percent. National per-visit rates are not subject to the 3.79 percent reduction related to the nominal increase in case-mix. The CY 2012 national per-visit rates per discipline are shown in Table 15. The six home health disciplines are as follows:

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

TABLE 15: National Per-Visit Amounts for LUPAs (Not including the LUPA Add-On Amount for a Beneficiary's Only Episode or the Initial Episode in a Sequence of Adjacent Episodes) and Outlier Calculations Updated by the HH PPS Payment Update Percentage, Before Wage Index Adjustment

		For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
Home Health Discipline Type	CY 2011 Per-Visit Amounts Per 60-Day Episode	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent	CY 2012 per-visit payment	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent minus 2 percentage points (-0.6 percent)	CY 2012 per-visit payment
HH Aide	$50.42	X 1.014	$51.13	X 0.994	$50.12
MSS	$178.46	X 1.014	$180.96	X 0.994	$177.39
OT	$122.54	X 1.014	$124.26	X 0.994	$121.80
PT	$121.73	X 1.014	$123.43	X 0.994	$121.00
SN	$111.32	X 1.014	$112.88	X 0.994	$110.65
SLP	$132.27	X 1.014	$134.12	X 0.994	$131.48

d. LUPA Add-On Payment Amount Update

Beginning in CY 2008, LUPA episodes that occur as the only episode or initial episode in a sequence of adjacent episodes are adjusted by adding an additional amount to the LUPA payment before adjusting for area wage differences. We update the LUPA payment amount by the CY 2012 HH PPS payment update percentage of 1.4 percent. The LUPA add-on payment amount is not subject to the 3.79 percent reduction related to the nominal increase in case-mix. For CY 2012, we update the add-on to the LUPA payment to HHAs that submit the required quality data by the CY 2012 HH PPS payment update percentage of 1.4 percent. The CY 2012 LUPA add-on payment amount is shown in Table 16. We update the add-on to the LUPA payment to HHAs that do not submit the required quality data by the CY 2012 HH PPS payment update percentage (1.4 percent) minus two percentage points, for a –0.6 percent update.

TABLE 16: CY 2012 LUPA Add-On Amounts

	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
CY 2011 LUPA Add-On Amount	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent	CY 2012 LUPA Add-On Amount	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent minus 2 percentage points (-0.6 percent)	CY 2012 LUPA Add-On Amount
$93.31	X 1.014	$94.62	X 0.994	$92.75

e. Nonroutine Medical Supply Conversion Factor Update

Payments for nonroutine medical supplies (NRS) are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. We increase CY 2011 NRS conversion factor ($52.54) by the CY 2012 HH PPS payment update percentage of 1.4 percent. The final updated CY 2012 NRS conversion factor for 2012 appears in Table 17. For CY 2012, the NRS conversion factor is $53.28.

TABLE 17: CY 2012 NRS Conversion Factor for HHAs that DO Submit the Required Quality Data

CY 2011 NRS Conversion Factor	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent	CY 2012 NRS Conversion Factor
$52.54	X 1.014	$53.28

Using the NRS conversion factor ($53.28) for CY 2012, the payment amounts for the various severity levels are shown in Table 18.

TABLE 18: CY 2012 NRS Payment Amounts for HHAs that DO Submit the Required Quality Data

Severity Level	Points (Scoring)	Relative Weight	CY 2012 NRS Payment Amount
1	0	0.2698	$14.37
2	1 to 14	0.9742	$51.91
3	15 to 27	2.6712	$142.32
4	28 to 48	3.9686	$211.45
5	49 to 98	6.1198	$326.06
6	99+	10.5254	$560.79

For HHAs that do not submit the required quality data, we again begin with the CY 2011 NRS conversion factor. We increase the CY 2011 NRS conversion factor ($52.54) by the CY 2012 HH PPS payment update percentage of 1.4 percent minus 2 percentage points, or –0.6 percent. The CY 2012 NRS conversion factor ($52.22) for HHAs that do not submit quality data is shown in Table 19.

TABLE 19: CY 2012 NRS Conversion Factor for HHAs that DO NOT Submit the Required Quality Data

CY 2011 NRS Conversion Factor	Multiply by the CY 2012 HH PPS payment update percentage of 1.4 percent minus 2 percentage points (-0.6 percent)	CY 2012 NRS Conversion Factor
$52.54	X 0.994	$52.22

The payment amounts for the various severity levels based on the updated conversion factor ($52.22) for HHAs that do not submit quality data are calculated in Table 20.

TABLE 20: CY 2012 NRS Payment Amounts for HHAs that DO NOT Submit the Required Quality Data

Severity Level	Points (Scoring)	Relative Weight	NRS Payment Amount
1	0	0.2698	$14.09
2	1 to 14	0.9742	$50.87
3	15 to 27	2.6712	$139.49
4	28 to 48	3.9686	$207.24
5	49 to 98	6.1198	$319.58
6	99+	10.5254	$549.64

5. Rural Add-On

Section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173, enacted on December 8, 2003 and as amended by section 3131(c) of the Affordable Care Act) provides an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010 and before January 1, 2016. The statute waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to home health services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

The 3 percent rural add-on is applied to the national standardized 60-day episode rate, national per-visit rates, LUPA add-on payment, and NRS conversion factor when home health services are provided in rural (non-CBSA) areas. Refer to Tables 21 thru 25 for these payment rates.

BILLING CODE 4120–01–P

TABLE 21: CY 2012 Payment Amounts for 60-Day Episodes for Services Provided in a Rural Area Before Case-Mix and Wage Index Adjustment

For HHAs that DO Submit Quality Data			For HHAs that DO NOT Submit Quality Data		
CY 2012 National Standardized 60-Day Episode Payment Rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 National Standardized 60-Day Episode Payment Rate	CY 2012 National Standardized 60-Day Episode Payment Rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 National Standardized 60-Day Episode Payment Rate
$2,138.52	X 1.03	$2,202.68	$2,096.34	X 1.03	$2,159.23

TABLE 22: CY 2012 Per-Visit Amounts for Services Provided in a Rural Area, Before Wage Index Adjustment

	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
Home Health Discipline Type	CY 2012 per-visit rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 per-visit rate	CY 2012 per-visit rate	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 per-visit rate
HH Aide	$51.13	X 1.03	$52.66	$50.12	X 1.03	$51.62
MSS	$180.96	X 1.03	$186.39	$177.39	X 1.03	$182.71
OT	$124.26	X 1.03	$127.99	$121.80	X 1.03	$125.45
PT	$123.43	X 1.03	$127.13	$121.00	X 1.03	$124.63
SN	$112.88	X 1.03	$116.27	$110.65	X 1.03	$113.97
SLP	$134.12	X 1.03	$138.14	$131.48	X 1.03	$135.42

TABLE 23: CY 2012 LUPA Add-On Amounts for Services Provided in Rural Areas

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2012 LUPA Add-On Amount	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 LUPA Add-On Amount	CY 2012 LUPA Add-On Amount	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 LUPA Add-On Amount
$94.62	X 1.03	$97.46	$92.75	X 1.03	$95.53

TABLE 24: CY 2012 NRS Conversion Factor for Services Provided in Rural Areas

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2011 Conversion Factor	Multiply by the 3 Percent Rural Add-On	Rural CY 2012 Conversion Factor	CY 2012 Conversion Factor	Multiply by the 3 Percent Rural Add-On	CY Rural 2012 Conversion Factor
$53.28	X 1.03	$54.88	$52.22	X 1.03	$53.79

TABLE 25: CY 2012 NRS Payment Amounts for Services Provided in Rural Areas

		For HHAs that DO submit quality data (NRS Conversion Factor=$54.88)		For HHAs that DO NOT submit quality data (NRS Conversion Factor=$53.79)	
Severity Level	Points (Scoring)	Relative Weight	Total NRS Payment Amount for Rural Areas	Relative Weight	Total NRS Payment Amount for Rural Areas
1	0	0.2698	$14.81	0.2698	$14.51
2	1 to 14	0.9742	$53.46	0.9742	$52.40
3	15 to 27	2.6712	$146.60	2.6712	$143.68
4	28 to 48	3.9686	$217.80	3.9686	$213.47
5	49 to 98	6.1198	$335.85	6.1198	$329.18
6	99+	10.5254	$577.63	10.5254	$566.16

BILLING CODE 4120–01–C

E. Therapy Corrections and Clarifications

1. Therapy Technical Correction to Regulation Text

In the CY 2012 HH PPS proposed rule (76 FR 41023 through 41024), we noted that regulation text at § 409.44(c)(2)(i)(D)(2) associated with changes we made to our regulations for CY 2011 required a technical correction. This technical correction was to change the word ''before'' in this regulation to the phrase ''no later than'' such that the final wording would read, ''Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide the therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) during the visit which would occur close to but no later than the 19th visit per the plan of care.''

2. Occupational Therapy Policy Clarifications

We also proposed (76 FR 41024) to clarify when occupational therapy would be considered a dependent service versus when it would be considered a qualifying service under the Medicare home health benefit, explaining the history of occupational therapy as a skilled yet dependent service under the benefit. We highlighted key regulations that explain the status of occupational therapy and clarified the status of when occupational therapy becomes a qualifying service by proposing to change the regulation text at § 409.42(c)(4) to establish exactly when occupational therapy becomes a qualifying service. We proposed to amend § 409.42(c)(4) to state that occupational therapy services that meet the requirements of § 409.44(c) initially qualify for home health coverage as a dependent service as defined in § 409.45(d) if the beneficiary's eligibility for home health services was established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period. Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) would be considered qualifying services.

We also proposed a change to § 409.44(c) to include a technical correction to this regulation text. We proposed to correct ''(c)(1) through (4)'' to, ''(c)(1) and (2),'' which is the correct reference.

The following is a summary of the comments we received regarding the therapy corrections and clarifications.

Comment: All commenters were supportive of or neutral toward the policy clarification regarding when occupational therapy becomes a qualifying service. Among these comments, some requested we further clarify whether occupational therapy can continue to be the qualifying service when the need for occupational therapy spans into a subsequent episode. One commenter asked for further clarification regarding when occupational therapy must be followed by a skilled nursing, physician therapy, or speech therapy service. Another commenter urged CMS to follow up this policy clarification with detailed explanations in the Medicare Benefit Policy Manual, including through the use of examples. Another commenter expressing agreement with our policy clarification, equated the clarifying policy with the elimination of the requirement that an original qualifying service must complete at least one covered visit after the initial dependent occupational therapy visit.

Response: We thank commenters for their positive response to our clarification of when occupational therapy becomes a qualifying service.

Because some commenters have suggested that the regulation text could be clarified for episodes beyond the initial episode for patients receiving more than one episode of home health, we are revising § 409.42(c)(4) to further clarify the regulation text in this final rule.

In response to the commenter who stated that the proposed policy removed the requirement that an original qualifying service must complete at least one covered visit after the initial dependent occupational therapy visit, we note that the commenter's interpretation of the proposed policy is not accurate as we will describe below. In response to the commenter who requested further clarification regarding when occupational therapy must be followed by a skilled nursing, physician therapy, or speech therapy service, we clarify that the initial occupational therapy service must be followed by another qualifying service to be covered. Subsequent occupational therapy services, however, do not require another qualifying service to follow them. Specifically, we are clarifying that once a beneficiary's eligibility for home

health services has been established by virtue of a prior need for an intermittent skilled service (that is, skilled nursing care, physical therapy, or speech-language pathology therapy), and the beneficiary also meets each of the criteria specified in § 409.44(c), the first occupational therapy service provided to the patient is considered a dependent service. We note that § 409.45(a) describes that in order for Medicare to cover a dependent service, the service must be followed by a qualifying skilled service, which meets the criteria in § 409.44(c), except when certain unexpected circumstances occur, such as an unexpected inpatient admission or the death of the beneficiary. As such, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, speech-language pathology service, or physical therapy service which meet the criteria in § 409.44(c), unless the exceptional circumstance criteria is met. Once that requirement for covered occupational therapy has been met, all subsequent occupational therapy services that meet the criteria in § 409.44(c) are considered to be qualifying, both in the current and in subsequent certification periods (subsequent adjacent episodes). Once occupational therapy has become a qualifying service, it remains a qualifying service from that point on as long as the services continue to meet the criteria in § 409.44(c). Therefore, there is no need for another qualifying skilled service to follow a covered qualifying occupational therapy service at the end of a home health episode. It is possible for covered qualifying occupational therapy services to exist at the end of an initial episode for a given beneficiary, if all of the above described requirements/criteria are met, without additional qualifying skilled nursing care, physical therapy, or speech-language pathology services following that covered qualifying occupational service. We plan to include these clarifications in Pub. 100–02, Chapter 7, Medicare Benefit Policy Manual.

Comment: We received several comments regarding the therapy reassessment requirements finalized with the CY 2011 HH PPS final rule. Some commenters called for CMS to stop all or part of the requirements. A number of commenters expressed their belief that with the 13th and 19th reassessment visit requirement, the 30-day reassessment requirement is not needed. These commenters stated the same exceptions permitted for the 13th and 19th-reassessment visit policy should apply to the 30-day reassessment policy as well to make it more flexible. A few commenters gave hospitalizations as an example of when there should be an exception to the 30-day reassessment requirement, noting that sometimes when home health patients are admitted to the hospital, the hospital might be delayed several days in contacting the HHA or not contact the HHA at all. One commenter questioned the logic of these therapy regulations, suggesting that they decrease the productivity of therapists and other home health staff, leading to agencies having to hire more staff to cover the needs of the aging population. Many commenters stated the therapy requirements are causing an undue burden on agencies while interfering with quality therapy care that a patient receives. Another commenter suggested that these therapy policies have had the opposite effect of what we intended because agencies that previously did not use therapy assistants are now using them more due to the increased costs associated with our policies. Among the alternatives that commenters proposed were to have reassessments required every 14 days, every 12–15 days for the first 30 days and then at least every 30 days, and between days 15–21 and 29–35 (that is, within the 3rd and 5th weeks of the episode).

Among those commenters who referred to the issues of administrative burden and inefficiency, especially in light of State licensure requirements for therapists (for example, New York requires PTAs must be supervised every 6 visits or every 30 days, whichever comes first), one commenter mentioned adding a 0.5 full time equivalent (FTE) for clinical auditing and 1 FTE as a scheduler to assure appropriate scheduling and track compliance. Some commenters suggested that the policy requires too many assessments; speaking of multiple-therapy cases, one commenter stated that these excessive assessments lead to lumping back-to-back assessments by multiple therapists. The commenter also suggested that due to our recalibration of therapy weights that de-emphasize high-therapy episodes less than before, these 13th and 19th-reassessment visits are no longer needed. One commenter stated that a physical therapist is expected to document for an occupational therapist. Another commenter recommended that we reconvene a technical expert panel to examine the appropriate use of therapy assistants and nursing personnel under the benefit to verify whether use of therapy assistants in particular is clinically inappropriate. The commenter also provided detailed explanations on the role of therapists and therapy assistants and how they interact with one another in such areas as communication, decision-making, and patient care delivery. The commenter also provided detailed recommendations on how the therapy CY 2011 policies can be better communicated, including through manual additions and revisions, and additional Questions and Answers. This commenter noted that some of the confusion over the 13th and 19th-visit requirements has to do with whether the ''count'' includes both covered and non-covered visits. Last, this commenter suggested that no additional changes to our therapy policies be made until a technical evaluation panel (TEP) can develop an alternate payment system for therapy alone. This commenter and another requested that CMS provide additional training for therapists and HHAs regarding these therapy requirements.

Response: We thank the commenters for their feedback, but note that the comments regarding the therapy reassessment requirements from the CY 2011 HH PPS final rule (75 FR 70372) are outside of the scope of this rule. However, we are further clarifying our policies and respond to comments regarding the administrative burden of these requirements and the suggestion that due to our recalibration of therapy weights that these requirements are no longer needed. We respectfully remind commenters that our reasons for the therapy reassessments outlined in the CY 2011 HH PPS final rule were not only to address payment vulnerabilities that have led to high use and sometimes overuse of therapy services, but also to ensure more qualified therapist involvement for beneficiaries receiving high amounts of therapy which evidence shows results in better patient outcomes. We note again, as we did in the CY 2011 HH PPS final rule (75 FR 70390 through 70391), that 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) provide support for our therapy policies. 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.

We also note that even with reductions in payments for high-therapy episodes, HHAs receive higher payments for these episodes than other episodes. We continue to believe that the requirement for a qualified therapist (instead of an assistant) to perform the needed therapy service at key points in a patient's course of treatment, as well as to assess, measure and document the effectiveness of the therapy provided promotes more effective and efficient care. Regarding the issue of the at least every 30-days reassessment requirement and hospitalizations, we also note that through a recently-posted Question and Answer, available at *http://www.cms.gov/HomeHealthPPS/Downloads/Therapy_Questions_and_Answers.pdf,* we have allowed for one exception to the 30-day reassessment requirement (that is, when there is a hold on therapy due to the patient's hospitalization for an unexpected change in the patient's condition). As we stated in this question and answer, we believe that the policy that requires a qualified therapist to perform the necessary therapy service, assess the patient, measure, and document the effectiveness of the therapy at least once every 30 days during a course of therapy treatment is essential to ensuring that effective, reasonable, and necessary therapy services are being provided to the patient. In the case of a home health patient where the therapy goals in the plan of care have not been met, but the doctor has instead ordered a temporary interruption in therapy, we would usually expect that the unique clinical condition of the patient would enable the HHA to anticipate that an interruption in therapy may be needed. In such cases, the HHA should ensure that the requirements are met earlier than the end of the 30-day period to ensure the HHA meets the 30-day requirement.

Where unexpected sudden changes in the patient's condition result in a need to stop therapy, we would expect to see documentation and evidence in the medical record which would support an unexpected change in the patient's condition which precludes delivery of the therapy service. We will modify our manual to describe that in such documented cases, the 30-day qualified therapist visit/assessment/measurement requirement can be delayed until the patient's physician orders therapy to resume.

We also note in response to the commenter that stated a physical therapist would be asked to do the assessment for an occupational therapist that, as we stated in the CY 2011 HH PPS final rule (75 FR 70392), in§ 409.44(c)(2)(i)(A), we clarified that our expectation is that only the therapist of his or her own corresponding discipline should complete the reassessment for that therapy discipline. Because we recognize that agencies and therapists continue to have questions on how to count therapy visits to determine when the required therapy assessment visits (which are to occur close to both the 14th and 20th Medicare-covered therapy visits but no later than the 13th and 19th Medicare-covered therapy visits) should occur, we have provided a clarification in § 409.44(c)(2)(i)(C)(*2*) and § 409.44(c)(2)(i)(D)(*2*) that from a Medicare payment perspective, only Medicare-covered visits are to be considered and counted. Specifically, to reflect that Medicare payment policy recognizes only Medicare-covered visits, we are inserting the words, ''Medicare-covered'' before the words, ''therapy-visit'' in both these regulations related to multiple therapy disciplines being provided because commenters have expressed confusion over the process of counting at both of these junctures. We have also inserted the words, ''the 14th Medicare-covered therapy visit'' at § 409.44(c)(2)(i)(C)(*2*) and the words, ''the 20th Medicare-covered therapy visit'' at § 409.44(c)(2)(i)(D)(*2*) to further reinforce that the counting of therapy visits for Medicare payment purposes should include only those Medicare-covered visits which are close to the 14th and 20th Medicare-covered therapy visits, but no later than the 13th and 19th Medicare-covered therapy visit. Last, to further address commenters' confusion, we have made minor changes to the regulation text to make the language between § 409.44(c)(2)(i)(C)(*2*) and 409.44(c)(2)(i)(D)(*2*) consistent.

We note that the counting of therapy visits for Medicare payment purposes might differ from how agencies and therapists would count therapy visits for a patient's plan of care. Consequently, we have also removed the references to the patient's ''plan of care'' in § 409.44(c)(2)(i)(C)(*2*) and § 409.44(c)(2)(i)(D)(*2*). We also note that both Medicare-covered and non-covered visits are included on the Medicare home health claim forms, where they should continue to be designated as covered or non-covered. We conclude by stating that we are committed to continuing our provider education efforts related to these therapy policies.

Comment: Another commenter stated that there are situations in which a 30-day skilled therapist visit for assessment of therapy must be followed by yet another skilled therapist visit for reassessment based on the therapy threshold.

Response: Again, while this comment is outside of the scope of this rule, we would like to note that every time a qualified therapist performs the therapy service, assesses the patient, measures and documents the effectiveness of the therapy service for that therapy discipline, the 30-day clock is 'reset'. As such, a qualified therapist visit/assessment/measurement and documentation which satisfies the threshold requirement could also satisfy the 30-day requirement.

Comment: We received one comment from a physical therapist who provided an overview of the profession from the commenter's perspective, highlighting payment trends for therapists, depending on which type of entity therapists work for (for example, directly for a HHA or as a contractor or subcontractor). The commenter provided examples of personal employment experiences that substantiate our concerns regarding intentional overprescribing of therapy and inappropriate use of therapy assistants. Consequently, the commenter recommended program integrity policies for CMS' consideration.

Response: We thank this commenter for taking the time to provide such a thoughtful response and will share this commenter's suggestions with our program integrity colleagues.

3. Summarization of Final Policies

As a result of the comments we received, we will finalize our technical corrections to § 409.44(c) and § 409.44(c)(2)(i)(D)(*2*). We will also finalize our regulation text at § 409.42(c)(4) to reflect that subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) are considered to be qualifying services. In addition, we further clarify the intent of

this policy on when occupational therapy becomes a qualifying service by making the following change to § 409.42(c)(4) as it appeared in our proposed rule: We are adding the phrase, ''in the current and subsequent adjacent certification periods (subsequent adjacent episodes)'' to the first line of this regulation text after the words, ''Occupational therapy services.''. Last, as we summarized above, we further clarify the method for counting visits for the 13th and 19th reassessment visit requirements by adding the words, ''Medicare-covered'' and deleting the words, ''per the plan of care,'' at § 409.44(c)(2)(i)(C)(*2*) and § 409.44(c)(2)(i)(D)(*2*).

F. Home Health Face-to-Face Encounter

As described in the CY 2011 HH PPS final rule (75 FR 70427), section 6407(a) of the Patient Protection and Affordable Care Act, as amended by section 10605 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended the requirements for physician certification of home health services contained in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act by requiring that, as a condition for payment, prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or a permitted nonphysician practitioner (NPP) has had a face-to-face encounter with the patient.

However, we believe that the statute does not preclude a patient's acute or post-acute physician from informing the certifying physician regarding their experience with the patient for the purpose of the face-to-face encounter requirement, as an NPP can. Instead, we believe that for patients admitted to home health following discharge from an acute or post-acute stay, the statutory language contains an unintentional gap in that it does not explicitly include language which allows the acute or post-acute attending physician to inform the certifying physician regarding his or her face-to-face encounters with the patient.

Therefore, for patients admitted to home health upon discharge from a hospital or post-acute facility, we proposed to allow the physician who cared for the patient in an acute or post-acute facility to inform the certifying physician regarding their encounters with the patient to satisfy the face-to-face encounter requirement, much like an NPP currently can.

The following is a summary of the comments we received regarding the home health face-to-face encounter proposal.

Comment: Several commenters expressed concern regarding scenarios where a face-to-face encounter occurs late. Specifically, commenters believe that when the encounter occurs more than 30 days after the episode start, that CMS should allow providers the flexibility to restart the episode with the start of care date within 30 days of the face-to-face encounter. Commenters described longstanding CMS policy that has allowed such restarting of the episode for Medicare payment purposes in certain situations beyond the agency's control. Commenters described that longstanding claims processing manual guidance has always allowed some flexibility in the OASIS completion in targeted scenarios, such as when a patient's payer source changes from Managed Care to Medicare fee-for-service (FFS). At times, the HHA is not notified timely that such a payer change has occurred. Commenters described that this same payer change scenario may result in a late face-to-face encounter, which is a Medicare FFS requirement. Allowing OASIS flexibility in targeted scenarios enables the provider to begin to bill Medicare at the point in time when all Medicare eligibility criteria are met.

Response: We thank the commenters for their comment and while this comment is outside the scope of this rule, we are taking this opportunity to clarify the policy. Conditions of participation regulations at § 484.55 require HHAs to complete a comprehensive assessment for each patient no later than 5 days after the start of care. In the scenarios described by the commenter, there exists a comprehensive assessment which includes the OASIS assessment which was completed within 5 days of the agency providing care to the patient. However, Medicare FFS eligibility was not met until later. We acknowledge that longstanding guidance in Section 80 of Chapter 10 of the Medicare Claims Processing Manual states that if a Medicare beneficiary changes from a different pay source to Medicare FFS, a new start of care OASIS assessment must be completed that reflects a start of care date equal to the start of the beneficiary's change to Medicare FFS. The manual allows for this OASIS completion flexibility in targeted situations, to meet both Medicare billing and eligibility rules. In these cases, the OASIS which was completed to satisfy the Medicare billing and eligibility requirement could have a completion date which is later than 5 days after the start of care date. We believe a late face-to-face encounter is another of these targeted situations which justifies OASIS completion flexibility. Specifically, where a face-to-face encounter did not occur within the 90 days prior to the start of care or within 30 days after the start of care, a provider may complete another OASIS with a start of care date equal to the date when all Medicare eligibility is met. However, Medicare will not pay for services provided before the date of eligibility.

Comment: Some commenters suggested that, if a face-to-face encounter does not occur within 30 days of the start of care, CMS should shift the burden of responsibility away from the HHA for financial loss and include physician communication requirements as a component of the CMS initiatives associated with the transition of care. Commenters suggested that the financial burden of the face-to-face documentation alone has significantly added to HHAs' operating costs. Other commenters stated the face-to-face requirement presents such an administrative burden that HHAs have had to add full-time staff to track the documentation requirements.

Response: We thank the commenters for their comments but these comments are outside the scope of this rule. However, we would like to remind commenters that we do not have the statutory authority to exempt HHAs from responsibility for the face-to-face encounter requirement, as the Affordable Care Act mandates that it is a condition for payment.

Comment: Some commenters requested that, due to difficulties securing documentation and physician refusal to write a narrative documenting why the patient needs skilled services and why the patient is homebound, the face-to-face documentation requirement should be limited to the statements that the patient needs skilled services and is homebound, and that the primary reason for home health services was addressed in the encounter, accompanied by the physician's signature and date. Another commenter suggested that CMS allow NPPs to document and sign the face-to-face documentation. Some commenters asked CMS to allow the narrative on a patient's plan of care to satisfy the documentation requirement. Other commenters suggested that CMS require a universal format of documentation to prevent Medicare contractor payment denials. Commenters requested that the face-to-face documentation be reduced to a check box on the plan of care or the Form 485. One commenter suggested that a separate, single certification form

be used for patients referred from the hospital to home care.

Response: We thank the commenters for their comments but these comments are outside the scope of this rule. However, we will briefly respond to the commenters' questions to ensure that commenters clearly understand the law and the policy. We would like to remind commenters that the law requires the certifying physician to document that the physician or an allowed NPP has had a face-to-face encounter with the patient. As such, a change in the statute would be required to allow an NPP to document the encounter. In response to the commenters who suggested that a standard form which contains checkboxes should be allowed to satisfy the documentation requirement and the commenter who asked CMS to allow the physician to simply sign a standard statement that the patient needs skilled services and is homebound, in our view, these suggestions would not satisfy the statutory requirement that the certifying physician document the encounter itself. We have reviewed forms which contained generic questions with checkboxes for the physician to simply check off and sign. We believe that such a form would not satisfy the documentation mandate in the law. Similarly, we believe a form that contains a pre-printed statement that the patient is homebound and needs skilled services which the physician would sign, as one commenter suggested, would also not meet the statutory requirement. Further, documentation which was drafted by another commenter which the physician would sign also would not meet the requirement. In using the words ''document the encounter'' in the statute instead of ''attest to the encounter,'' we believe that the Congress intended the certifying physician to include factual information about the patient's condition as seen during the encounter which would support the physician's certification of the patient's eligibility (homebound status and the need for skilled services).

We have provided certifying physicians the flexibility to generate the documentation from their electronic medical record entries concerning the patient. The physician's own medical record entries would contain the factual information about the patient's condition as seen during the encounter. We also allow the physician's support staff to extract the documentation from the physician's medical record entries for the physician's signature. We accept documentation which was generated or extracted from a physician's medical record, assuming it contains all the required content, regardless of what format it is in, even when that generated format contains checkboxes. Additionally, as we describe in more detail later in this section, if an allowed practitioner other than the certifying physician performs the encounter, the certifying physician may incorporate the practitioner's communication regarding the patient's clinical condition as part of the certifying physician's documentation.

In response to the commenter who requested that the physician's narrative on the plan of care satisfy the documentation requirement, we note that this would be acceptable in certain cases. As described above, we do not mandate that the documentation be in any particular format. We do require that the content requirements be met. We would expect that a physician's orders referring the patient to home health could satisfy some or all of the documentation content requirements. However, as stated above, we believe the law would not allow an HHA to draft the documentation for the physician to sign. CMS is aware that often HHAs will draft the plan of care narrative for the physician to sign. In these cases, the plan of care narrative would not satisfy the documentation requirement because the narrative is drafted by the HHA instead of the physician, and is based on the HHA's assessment of the patient, not the physician's encounter.

In response to the commenters who requested that CMS require a universal format for the documentation, we note that since 2002, we have not mandated the use of a specific form when physicians certify a patient's eligibility for Medicare's home health benefit. Instead, we allow physicians and HHAs to meet the certification documentation requirements in a way that utilizes their respective practice documentation system, and gives providers flexibility to use electronic medical record software.

Comment: We received comments that the face-to-face requirement presents an unnecessary barrier to care for all patients, but especially for bed bound patients who need ambulance transportation to physician appointments. Also, a commenter suggested that the Affordable Care Act be revised to expand the definition of telehealth services to allow individuals to meet the face-to-face requirements through technologies available in their homes. A commenter suggested that telehealth could be used to satisfy the face-to-face encounter, and asked CMS to revise its regulations so that the patient's home could be a telehealth originating site. Further, some commenters requested that CMS immediately halt the face-to-face requirement. Some commenters requested that the requirement be revised to establish exemptions to the face-to-face encounter for post-acute home health patients or those patients with barriers to physician care. We also received comments asking CMS to expand the current face-to-face timeframes.

Response: We thank the commenters for their input but these comments are outside the scope of this rule. However, we will take the opportunity to briefly respond to the commenters to ensure better understanding of the statute. We would like to remind commenters that the face-to-face requirement is only required for initial certifications, not recertifications. In response to the commenters who asked us to halt or change the provision, we would not have the authority to do so. In response to the commenter who asked CMS to revise its regulation to add the home as a telehealth originating site, we note that section 1834(m) of the Act limits those sites where a telehealth service can be provided. Regarding the timeframe of the face-to-face requirement, we believe the current timeframe of 90 days prior to the start of care and 30 days after the start of care is appropriate and best meets the program integrity and quality goals associated with the provision.

Comment: Some commenters requested the elimination of the face-to-face requirement for patients admitted to home health within certain timeframes of hospital discharges. Commenters stated that patients who are discharged from a hospital have clearly seen a physician and discharge planning team who determined home health to be an appropriate post-discharge follow-up. Commenters believed that the intent of this provision, which is a program integrity provision, is to ensure that the patient recently saw his or her physician.

Response: We thank the commenters for their suggestions. However, this exemption would violate the statutory mandate. We do not have the authority to exempt post-acute home health admissions from the face-to-face encounter requirement.

Comment: We received comments questioning whether or not the acute or post-acute physician will still be allowed to initiate the plan of care, perform and document the face-to-face encounter, certify the patient's home health eligibility, and ''hand off'' the plan of care to the patient's community physician. Commenters were confused by the proposed regulation text language

at § 424.22(a)(1)(v)(A) stating that the acute or post-acute physician ''must'' inform the certifying physician of the face-to-face encounter clinical findings. As the proposed regulatory text reads, commenters believed the use of ''must'' indicated that an attending acute or post-acute physician must inform the certifying physician of the findings from the face-to-face encounter rather than being able to perform the encounter, document the encounter and certify home health eligibility himself or herself.

Response: We thank the commenters for their comments. The physician who cared for the patient in an acute or post-acute facility prior to the patient's home health admission can perform and document the face-to-face encounter and certify the patient's home health eligibility, initiate the plan of care, and hand off the plan of care to the patient's community physician. These physicians often complete the certification of home health eligibility for a patient, which now includes the face-to-face documentation. In this rule, we simply proposed additional flexibility for the physician who cared for the patient in an acute or post-acute facility to inform the certifying physician of the patient's need for skilled services and homebound status in the same manner that an NPP can. To address any confusion that may exist, we will revise § 424.22(a)(1)(v)(A) to only require the physician who cared for the patient in the acute or post-acute facility to inform the certifying physician when the physician who cared for the patient in the acute or post-acute facility is not the certifying physician.

Comment: A commenter suggested that in an acute or post-acute facility, a patient is often seen by many physicians and any of those physicians should be able to inform the certifying physician. Therefore, the commenter suggested that CMS consider removing the word ''attending'' from the regulation text and use the term ''acute'' or ''post-acute'' physician instead. The commenter described how a patient's home health initiation and supervision may be most appropriately managed by a specialist, primary care physician, hospitalist, or surgeon, irrespective of who is the attending physician.

Response: We found the comment compelling and will remove ''attending'' from the regulatory text. Instead, we will describe that a physician who cared for the patient in an acute or post-acute facility and who has privileges at the facility can inform the certifying physician regarding the patient's clinical condition. The certifying physician can use that information to document the face-to-face encounter.

Comment: Many commenters disagreed with the proposed rule to require a face-to-face encounter and supporting documentation for Medicaid patients.

Response: These comments are outside the scope of this rule. The Medicaid face-to-face provision was proposed in the Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health proposed rule published in the July 12, 2011 **Federal Register** (76 FR 41032).

Comment: We received comments supporting the added flexibility associated with the face-to-face encounter provision, given that physicians who care for the patient in an acute or post-acute facility are the most familiar with the patient's condition upon discharge, yet may not want the burden of designing a plan of care and certifying eligibility, and should be allowed to inform the physician as an NPP.

Response: We thank the commenters for their support.

Comment: We received a comment asking for CMS to include language in the final rule that clearly outlines that the HHA may assist with the communication between the physician who cared for the patient in an acute or post-acute facility, who performed the face-to-face encounter, and the certifying physician. We received comments asking CMS to clarify whether verbal and/or written or typed documentation qualifies as communication between the physician who cared for the patient in an acute or post-acute facility and the patient's certifying physician. Other commenters questioned whether the documentation of the face-to-face encounter must be in the HHA record.

Response: We thank the commenters for their comments. The HHA may facilitate communication between the physician who cared for the patient in an acute or post-acute facility and the patient's community physician. We note that this would be considered a part of the patient's care coordination. However, we reiterate that the HHA cannot draft the encounter documentation for the certifying physician to sign. Similarly, we note that the information flow/communications from the allowed NPP or physician who cared for the patient in an acute or post-acute facility to the certifying physician concerning the patient's condition cannot be altered by the HHA. For example, in most cases we would expect the patient's discharge plan to contain the information, from the allowed NPP or the physician caring for the patient in the acute or post-acute facility, needed by the certifying physician to document the encounter. We would expect that both the HHA and the patient's community physician (certifying physician) would receive the patient's discharge plan. When this does not occur, or it does not occur in a timely manner, the HHA can send a copy of the discharge plan to the certifying physician to expedite the information exchange. However, it would be unacceptable for the HHA to fill in missing clinical information concerning the patient, based on the HHA's assessment of the patient. The documentation must reflect the physician's (or NPP's) experience with the patient, not the HHA's. Regarding the commenters who asked for guidance on what sort of communication CMS expects would occur between the physician who cared for the patient in the acute or post-acute facility and the certifying physician, we do not require a specific communication protocol to occur between an NPP, or a physician who cared for the patient in an acute or post-acute facility, and the certifying physician. We intend for the communication between an NPP, or a physician who cared for the patient in an acute or post-acute facility, and the certifying physician to occur in a way that works best for the two health care professionals involved. We would expect that often the patient's discharge summary, even if not in the form of a discharge plan, with the information flow/communications from the allowed NPP or the physician who cared for the patient in the acute or post-acute facility, can serve as the face-to-face documentation so long as it includes the signature of the certifying physician and the required content. To address the commenter who asked whether or not the HHA needs to have the face-to-face encounter documentation on record, we remind the commenter that the face-to-face encounter documentation is part of the certification of eligibility and as such must be in the HHA's records.

Comment: Commenters stated that the face-to-face documentation is redundant, given the documentation of a patient's needs on the discharge plan and/or plan of care. Commenters questioned whether a certifying physician would need to rewrite the documentation of the face-to-face encounter rather than just review the information documented by the physician who cared for the patient in an acute or post-acute facility regarding the encounter. Commenters also

expressed concern that in the case of hospital support staff assisting in the documentation, the level of detail on a hospital patient's post-acute needs that is typically available in standard hospital medical record notes is not adequate to satisfy the face-to-face documentation requirements. Furthermore, commenters suggested that hospital-based physicians typically lack information on the criteria related to Medicare's homebound status and are not trained to make judgments on homebound status following discharge. Commenters suggested that the proposed additional flexibility needs to be integrated with existing discharge processes. Other commenters suggested that once the patient is discharged from the hospital, the hospitalist no longer feels accountable for the patient. Commenters were concerned that patients may be denied access to home health services in cases where collaboration between the physician who cared for the patient in an acute or post-acute facility and the certifying physician is not timely, because the certifying physician might be unable to obtain the needed documentation information. We also received comments that this added flexibility will add to an already strained relationship between the acute or post-acute physician and the community physician since they will be doing each other's work. Commenters suggested that the proposed flexibility will add a new burden to community physicians since they will not be paid for certifying the patient's eligibility for home health. Other commenters asked that CMS allow for community physicians to bill G0180 if the patient's physician who cared for the patient in an acute or post-acute facility is performing the face-to-face encounter and certifying home health eligibility.

Response: We thank the commenters for their comments. Regarding the commenter who asked whether the certifying physician must retype the acute or post-acute physician's documentation on the certification form, we note that we allow for the face-to-face documentation to be part of the certification or an addendum to it. Therefore, it would be acceptable for the certifying physician (or his or her support staff) to attach a communication (such as a discharge summary) from an allowed NPP, or a physician who cared for the patient in an acute or post-acute facility, who performed the encounter to the certification as an addendum. If, for example, a discharge summary from a physician who cared for the patient in an acute or post-acute facility contains all of the needed documentation content, the certifying physician would simply need to sign and date the discharge summary and ensure it is attached as an addendum to the certification.

In response to the commenter who was concerned that acute physicians may not communicate a patient's homebound status to the certifying physician, we note that this additional flexibility does not change the documentation content requirements or change the requirement that the certifying physician must document the encounter. If the information sent to the certifying physician does not explicitly contain statements which describe why the patient requires skilled services and how the patient's condition supports homebound status, we would expect it to contain enough information regarding the patient's clinical condition for the certifying physician (or his or her support staff) to complete the documentation. A typical discharge summary would contain enough clinical information to enable the certifying physician to assess homebound status, for example. Where the information lacks the clinical detail which would enable the certifying physician to complete the documentation, we would expect the certifying physician or the physician's support staff to obtain the additional information from the physician who cared for the patient in an acute or post-acute facility, discharge planner, or the acute or post-acute physician's support staff. We would expect that most of the time, a phone call or electronic mail exchange between the physicians' support staffs would address gaps in information. In response to the commenters who were concerned that the information sharing might not occur in a timely manner or the information exchange would be burdensome to the community physician and may strain the community physician and acute or post-acute physician relationship, we note that we believe that this information sharing between the physician who cared for the patient in an acute or post-acute facility and the community physician who assumes care for the patient upon discharge (certifying physician) for the purposes of documenting the face-to-face encounter, is consistent with the sort of communication which occurs when any patient is discharged from an inpatient setting to the community. Discharge procedures generally require that the discharge plan includes the patient's clinical condition and that the discharge plan and supporting documentation be shared with the patient's follow-up care provider. Where the discharge plan is not sent to the certifying physician and instead is sent to the HHA, the HHA would forward a copy of the discharge plan to the certifying physician. We also note that the physician who completes and signs the certification of eligibility can bill Medicare using the G0180 code.

Comment: Commenters suggested that CMS should allow any physician to work with another physician colleague sharing the face-to-face encounter and documentation responsibilities, as well as the certification. Commenters also asked CMS to expand the physicians who may perform the face-to-face encounter to include partners or colleagues of the certifying physician or urgent care center physicians for non-acute inpatient settings. Further, a commenter stated that if a patient goes to an outpatient clinic appointment and sees an alternate physician, the alternate physician should be allowed to perform the encounter and inform the certifying physician of the patient's clinical condition, homebound status, and need for skilled services.

Response: We thank the commenters for their suggestions. While we are sensitive to the scenarios which the commenters describe, we do not believe we would have a strong justification to assert that the Congress intended to allow any physician to inform the certifying physician and as such, we believe we would not have the statutory authority to allow this additional flexibility. We note that the Medicare home health benefit relies on the patient's physician to determine eligibility for home health services. This type of physician involvement is critical from both a quality of care and program integrity perspective. Prior to enactment of the face-to-face encounter provision, the patient's physician often relied on information provided by an HHA when making decisions about patient care. The Affordable Care Act established the requirement for a physician face-to-face encounter prior to certifying a patient's eligibility for home health services, along with other program integrity provisions, to address concerns surrounding ineligible patients receiving home health services and concerns that physicians who had no firsthand knowledge of the patient's clinical condition were certifying the patient's eligibility for home health. Additionally, in the CY 2011 HH PPS final rule, we described research which showed fewer re-hospitalizations when the home health patient had a recent encounter with the physician responsible for the home health care plan. We also refer the commenters to

the CY 2012 HH PPS proposed rule (76 FR 41024 through 41025), where we described our reasons for believing that the Congress did not intend to exclude physicians who care for the patient in an acute or post-acute facility from informing the certifying physician regarding their recent encounters with the patient as the Congress allowed certain NPPs to do. We described why we believed that in adding this flexibility, we are increasing communication between HHAs and physicians, why we believed that adopting this flexibility introduced no program integrity risks or quality concerns and why we believed the flexibility is consistent with the goals of the law, including the goal of achieving more physician involvement with the patient when ordering home health services. If the hospital physician is unwilling to certify a patient's eligibility for home health, the hospital discharge plan sent to the certifying physician would contain current clinical information regarding the patient, enabling the certifying physician to make determinations regarding the patient care. However, we do not believe that a similar strong argument exists that the Congress intended to allow any physician to inform the certifying physician. As such, we would not have the statutory authority to allow this additional flexibility.

Comment: Commenters suggested that CMS study transitions from hospitals to home care to evaluate whether the face-to-face improves care coordination, discourages home health utilization by patients who do not qualify for Medicare-covered home health services, or contributes to preventing or delaying access to medically necessary home care. Other commenters suggested that CMS regularly meet with the NAHC for industry input. Commenters also suggested that CMS has not provided adequate education to the physician community and should consider initiatives such as Patient Care Transitions and Accountable Care to manage a more widespread effort for physician communication. Another commenter noted that CMS' Web-based ''Frequently Asked Questions'' (FAQ) for provider clarity are sporadically updated without notice and are seemingly ad hoc policy developments. A commenter also suggested that CMS date its policy guidance so that providers know which guidance is most recent.

Response: We thank the commenters for their comments but these comments are outside the scope of this rule. However, we will continue to work with the industry to educate providers and we will continue to monitor the effects of the face-to-face requirement.

Comment: We received a comment that a major issue with the face-to-face requirement is that patients should have the right to refuse a clinic visit that is not medically necessary.

Response: We thank the commenter for the comment but this comment is outside the scope of this rule. We would like to clarify, however, that the face-to-face requirement is a statutory requirement for payment. Further, we would expect that practitioners would typically be conducting a medically necessary service to the patient, and this service would also meet the face-to-face encounter requirement. We also remind the commenter that, to be eligible for the Medicare home health benefit, a patient must be under the care of a physician. Should a patient refuse to have a face-to-face encounter with the physician responsible for care, we would question whether the patient was legitimately under the care of the physician.

As a result of the comments, we will finalize the proposed implementation approach with the following revisions:

- We will remove ''attending'' from the regulatory language and add additional language at § 424.22(a)(1)(v) to describe physicians who qualify as the physician who cared for the patient in an acute or post-acute facility.
- We will revise § 424.22(a)(1)(v) so that the certifying physician's documentation of the face-to-face encounter clearly states that either the certifying physician himself or herself, the allowed NPP, or, for patients admitted to home health immediately after an acute or post-acute stay, a physician who cared for the patient in an acute or post-acute facility, has had a face-to-face encounter with the patient.
- We will add clarifying language to § 424.22(a)(1)(v)(A) to address scenarios where the physician who cared for the patient in an acute or post-acute facility performing the face-to-face encounter is also the certifying physician. We will revise § 424.22(a)(1)(v)(A) to describe that the NPP or the physician who cared for the patient in an acute or post-acute facility performing the face-to-face encounter must communicate the clinical findings of the encounter to the certifying physician, unless the physician who cared for the patient in an acute or post-acute facility is also the certifying physician.

We will finalize the above face-to-face encounter provisions for starts of care beginning January 1, 2012 and later.

G. Payment Reform: Home Health Study and Report

As we noted in our proposed rule (76 FR 41025), section 3131(d) of the Affordable Care Act requires the Secretary to conduct a study on HHA costs of providing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness (specifically, patients with ''high levels of severity of illness''). In our proposed rule, we provided a completed description of the varied areas for which we have the authority to explore as part of our payment reform activities (76 FR 41025 through 41026). We continue to plan for the study to evaluate the current HH PPS and develop payment reform options which might minimize vulnerabilities and more accurately align payment with patient resource costs to prepare the Report to Congress regarding the study that we must deliver no later than March 1, 2014.

In our proposed rule, we also highlighted multiple activities that included those associated with the development of a study analytic approach (76 FR 41025), as well as our progress to date. We have held a second technical evaluation panel (TEP) since publishing our proposed rule and plan to publish the TEP proceedings on the CMS Web Site in the coming weeks.

As we announced in the proposed rule, we anticipate awarding another contract that will build upon the foundation established. Specifically, this contract will include refinement of the analytic plan performance of the detailed analysis, and ultimately recommendations for payment model options. We will provide updates regarding our progress in future rulemaking and open door forums.

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

Comment: We received a number of comments expressing appreciation for the status report on our progress and future plans for the payment reform study. Commenters' specific suggestions for topics to incorporate into the study design and plan included the following: analysis and revisions for the HH PPS to more appropriately capture and align resource costs to payment among all the different service groups; research on the underutilization of therapy services in rural and underserved areas; and ways of improving physician interaction with home health patients separate from the face-to-face requirement. A few commenters expressed particular concern that the study explore the

hypothesis that a subset of HHAs, concentrated in the non-profit sector, have become safety net providers, continuing to offer access to those vulnerable patients that can be challenging and costly to serve, relative to HH PPS payments.

Response: We thank commenters for their expressed support of our efforts to date. We will attempt to include as many of the recommended areas of study as part of the final study design as possible, including those suggestions related to the outlier policy as we noted above in that section (see II.C. Outlier Policy). We will continue to solicit input from stakeholders as we develop the final study plan and provide periodic updates on our progress through multiple avenues such as the CMS Web Site and Open Door Forums.

Finally, we will continue to provide periodic updates on our progress.

H. International Classification of Diseases 10th Edition (ICD–10) Coding

In the CY 2012 HH PPS proposed rule, we discussed our preliminary plans to transition to the use of ICD–10–CM codes in October 2013. Based upon experience gained in our review of the ICD–10–CM codes we are striving to have the draft code lists out in the spring of 2012 versus October 2011. In addition, based upon comments received on our transition plans we are aiming to get the draft ICD–10–CM HHRG out on or before April 2013 versus the proposed July 2013 target contained in the proposed rule.

Effective March 17, 2009, we finalized our policies for the Health Insurance and Portability Accountability Act Administrative Simplification: Modifications to the Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS (74 FR 3328). The March 17, 2009 final rule modifies the standard medical data code sets for coding diagnoses by adopting the International Classification of Disease, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, including the Official ICD–10–CM Guidelines for Coding and Reporting. These new codes replace the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting. Entities are required to have implemented the adopted policies by October 1, 2013. On October 1, 2013, the ICD–9 code sets used to report medical diagnoses will be replaced by the ICD–10 code sets. In preparation for the transition to use of ICD–10–CM codes, CMS is currently undergoing extensive efforts to update the Medicare payment systems.

One of the key activities identified under this transition to ICD–10–CM codes is the need for CMS to review and update the payment systems which currently use ICD–9–CM codes. Home health agencies report ICD–9–CM codes for their patients through OASIS–C. The HHAs enter data (including the ICD–9–CM codes) collected from their patients' OASIS assessments into a data collection software tool. For Medicare patients, the data collection software invokes HH PPS Grouper software to assign a Health Insurance Prospective Payment System (HIPPS) code on the Medicare HH PPS bill, ultimately enabling CMS' claims processing system to reimburse the HHA for services provided to patients receiving Medicare's home health benefit. The HH PPS Grouper currently utilizes ICD–9–CM codes to calculate the HIPPS code. Effective October 1, 2013, the HH PPS Grouper will utilize the ICD–10–CM codes to calculate the HIPPS code.

We have been working with the HHRG maintenance contractor to revise the HHRG to accommodate ICD–10–CM codes, as well as identify the appropriate ICD–10–CM codes to be included in each diagnosis group within the HHRG. In addition, we have also contracted with Abt Associates to assist with resolving the transition of certain codes that may be mapped to more than one diagnosis code under ICD–10–CM.

To assist HHAs and their vendors in preparing for this transition, the Agency is committed to providing information for transitioning the HHRG to accommodate ICD–10–CM codes effective October 1, 2013. The Agency will update providers and vendors through the ICD–10–CM National Provider outreach calls on our conversion plans. Additional detail concerning teleconference registration is available at *http://www.cms.gov/ICD10/Tel10/list.asp?intNumPerPage=20&submit=Go.* Further details pertaining to our plans will be announced through the National Provider outreach calls.

We will provide a draft list of ICD–10–CM codes for the HHRG through the ICD–10 section of the Web site. Specific dates regarding our roll-out plans will be announced through the National Provider outreach calls. The preliminary plans include publishing the draft list of ICD–10–CM codes for the HHRG by the spring of 2012, for industry review, as well as describing our testing approach for the HHRG to accommodate and process ICD–10–CM codes through the ICD–10 section of the CMS Web site. In reviewing the list of proposed ICD–10–CM codes we have identified that more time is needed to complete our review and develop a draft lists for industry review. However, the release of the draft list in early 2012 permits ample time for consideration of any comments received to be taken into consideration during our development of the CY 2013 HH PPS proposed rule. The objective of the ICD–10–CM HHRG testing is to verify that all properly formatted input data containing ICD–10–CM diagnosis codes will produce the expected output. The HHRG maintenance contractor will convert current OASIS–C records to their translated ICD–10–CM codes to determine that appropriate outputs are achieved. CMS and the HHRG maintenance contractor will review the results of the testing to determine if additional testing is required.

In addition, in April 2013, we plan to share the ICD–10–CM HHRG software with those vendors and HHAs that have agreed to serve as Beta Testers and get their feedback regarding the software's functionality. We may expand the release of this draft version by releasing the draft ICD–10 HHRG to all interested parties. We are pursuing a wider release of the draft HHRG based upon comments received requesting that the agency release the draft HHRG to all interested parties. Issues and concerns noted will be reviewed and addressed by the HHRG Maintenance Contractor in consultation with CMS.

We plan to release the final version of the ICD–10–CM HHRG in July 2013 (or earlier if feasible) to permit HHAs and their vendors sufficient time to install the software. We will strive to release the final version of the ICD–10–CM HHRG as early as possible based upon comments received from the industry requesting an earlier release date.

The following is summary of the comments we received regarding the International Classification of Diseases 10th Edition (ICD–10) Coding.

Comment: One commenter suggested that CMS should consider an earlier release of the HHRG software which was proposed to be released to Beta Testers in April 2013. In addition, the commenter suggested that CMS should publish and make available the draft HHRG available to the entire industry for their review versus the current approach of soliciting input from vendors that have volunteered to review our HHRG.

Response: We appreciate the feedback provided and are committed to developing an earlier release of the HHRG if possible and will take into consideration the suggestion concerning industry wide release of the draft October 2013 ICD–10–CM HHRG. Final details concerning our implementation plans will be released through the scheduled Provider Outreach

teleconferences and posted on the ICD–10 section of the CMS Web site.

Comment: Several commenters' suggested that CMS has committed to publishing this information in a format that crosswalks the ICD–9–CM to ICD–10 codes.

Response: We have not reached any decisions regarding the format of the code lists. Additional information concerning the format will be provided through the ICD–10–CM provider outreach teleconferences and posted on the ICD–10 section of the CMS Web site.

Comment: Several commenter's noted their appreciation of our plans to release the proposed lists of ICD–10–CM codes as early as October 1, 2011.

Response: Based upon our current progress in reviewing the code lists developed by our support contracts and resolving potential conflicts, we will be revising the language in our final regulation. The regulation will reflect that the proposed lists of ICD–10–CM codes may be made available on the ICD–10 section of the CMS Web site in the spring of 2012.

As a result of the comments, we have made modifications to the language to indicate that we will take into consideration a commenters' suggestion that all interested parties should be included in the review of the draft ICD–10–CM HHRG. A final decision will be announced in a future ICD–10 Provider Outreach teleconference and posted on the ICD–10 section of the CMS Web site. In addition, the agency will consider the suggestion surrounding the format of the ICD–10 translation list and a final decision will be announced as outlined earlier in this section. Lastly, based upon our current experience in reviewing the ICD–10–CM codes we believe that the draft code list will not be made available on the ICD–10 section of the CMS Web site until early 2012.

I. Clarification To Benefit Policy Manual Language on ''Confined to the Home'' Definition

To address the recommended changes of the Office of Inspector General (OIG) to the home health benefit policy manual, CMS proposed to clarify its ''confined to the home'' definition to more accurately reflect the definition as articulated in the Act. We proposed to move the requirements that the patient require physical assistance to leave the home or if leaving home is medically contraindicated, and that the condition of the patient should be such that there exists a normal inability to leave home and, consequently, leaving the home would require a considerable and taxing effort to the beginning of section 30.1.1 of the Chapter 7 Home Health Benefit Policy Manual as necessary requirements to be considered ''confined to the home.'' Further, we proposed to remove vague terms from section 30.1.1, such as ''generally speaking,'' to ensure clear and specific requirements for the definition. These changes present the requirements first and more closely align our policy manual with the Act to prevent confusion and promote a clearer enforcement of the statute and more definitive guidance to HHAs for compliance. As such, we proposed that section 30.1.1 begin with the following, revised language:

''30.1.1—Patient Confined to the Home

For a patient to be eligible to receive covered home health services under both Part A and Part B, the statute requires that a physician certify in all cases that the patient is confined to his/her home. For purposes of the statute, an individual shall be considered ''confined to the home'' (that is, homebound) if the following exist:

(1) The individual has a condition due to an illness or injury that restricts his or her ability to leave their place of residence except with: the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

(2) The individual does not have to be bedridden to be considered ''confined to the home''. However, the condition of the patient should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort.

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers, licensed or certified by a State or accredited to furnish adult day-care services in the State, to receive therapeutic, psychological, or medical treatment;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, for example, an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists would be: * * *''

The following is a summary of the comments we received regarding clarification to benefit policy manual language on ''confined to the home'' definition.

Comment: Commenters were not clear on whether the individual needs to meet both of the requirements of (1) needing physical assistance to leave the home or if leaving home is medically contraindicated and (2) the condition of the patient being such that there exists a normal inability to leave home and, consequently, leaving the home would require a considerable and taxing effort; or if meeting either one of the requirements is acceptable. A commenter recommended adding ''and'' at the end of statement ''1'' to clarify.

Response: As the statute is written, statement ''1'' must first be met and then statement ''2'' must also be true about a patient to be considered homebound. We found this comment compelling and will add ''and'' to the end of statement ''1'' to better match the manual guidance to the statutory language and to more clearly distinguish the requirements. Therefore, it will be clear that, to be considered ''confined to the home'' a patient must first meet one of the requirements within statement ''1'' (if the patient requires physical assistance to leave the home or if

leaving home is medically contraindicated), and the individual must then also meet both of the requirements of statement ''2'' (the condition of the patient should be such that there exists a normal inability to leave home and, consequently, leaving the home would require a considerable and taxing effort).

Comment: Several commenters suggested that CMS add clarifying language differentiating absences from the home for entertainment versus those required to preserve independent living to prevent premature disqualification of otherwise eligible patients. Commenters also stated that the vagueness of the definition forces HHAs to submit post-payment demand bills to Medicare for Medicare/Medicaid dually eligible patients, even when the patient may not be confined to the home, causing administrative burden and waste. Further, commenters suggested that CMS provide guidance about this provision to State Medicaid offices to prevent inconsistent application and better control the administrative burdens. Still other commenters recommended removing the ''confined to the home'' definition to align with Medicaid. A commenter stated that the statement about not being bedridden is confusing.

Response: We believe the comments are out of the scope of the proposed rule. We only proposed to align the manual language with the statutory language at this time. Further clarification of the definition would need to be proposed through the rulemaking process. However, we will continue to work with the industry to better inform and educate about the requirements of the benefit.

Comment: We received comments suggesting that CMS leave the current definition in place so as to prevent the definition from becoming narrower and arbitrary. Further, commenters stated that the need for aid of a supportive device, the use of special transportation or the assistance of another person does not necessarily entail a normal inability to leave home and requiring a considerable and taxing effort to do so, which could lead to further misapplication of the benefit.

Response: We proposed to align the manual language to better mirror the statutory language with regard to the ''confined to the home'' definition, thereby intending to make the definition clearer and more consistent. However, we do not believe that the proposed clarification makes the homebound definition narrower and more arbitrary. Rather, the clarification moves the two requirements (one of which must be met) to the beginning of the manual guidance before further description of examples and exceptions.

Comment: We received support for the proposed clarification, maintaining that the clarification better addresses providers' concerns about how patients' occasional absences from the home affect their homebound status and eligibility for the home health benefit.

Response: We thank the commenters for their support.

As a result of the comments, we will finalize the proposed clarification of the manual language with the following exceptions: We are adding ''and'' to the end of statement ''1'' of the two requirements for homebound status to more clearly convey that to be considered ''confined to the home,'' the patient first must meet one of the following two requirements. The patient must either need physical assistance leaving the home or leaving is medically contraindicated. If the patient meets one of those requirements, the patient must then also meet the two additional requirements as follows: There must also be a normal inability to leave home and leaving the home must require a considerable and taxing effort.

III. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements. The information collection requirements discussed in proposed § 424.22 are currently approved under OMB control number 0938–1083. The information collection requirements discussed in proposed § 484.250, the OASIS–C and Home Health Care CAHPS, are currently approved under OMB control numbers 0938–0760 and 0938–1066, respectively. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

B. Statement of Need

This final rule adheres to the following statutory requirements. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled ''Prospective Payment For Home Health Services''. Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited CR data available to the Secretary, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services

furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(5) of the Act, as amended by section 3131 of the Affordable Care Act, gives the Secretary the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Also, section 3131 of the Affordable Care Act requires that HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent the payment amount otherwise made under section 1895 of the Act.

C. Overall Impact

The update set forth in this final rule applies to Medicare payments under HH PPS in CY 2012. Accordingly, the following analysis describes the impact in CY 2012 only. We estimate that the net impact of the proposals in this rule is approximately $430 million in CY 2012 savings. The $430 million impact due to the proposed CY 2012 HH PPS rule reflects the distributional effects of an updated wage index ($10 million increase) plus the 1.4 percent HH PPS payment update percentage ($280 million increase), for a total increase of $290 million. The 3.79 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($720 million decrease) plus the combined wage index and HH PPS payment update percentage ($290 million increase) results in a total savings of $430 million in CY 2012. The $430 million in savings is reflected in the first row of column 3 of Table 26 as a 2.31 percent decrease in expenditures when comparing the current CY 2011 HH PPS to the CY 2012 HH PPS.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to $34.5 million in any 1 year. For the purposes of the RFA, our updated data show that approximately 98 percent of HHAs are considered to be small businesses according to the Small Business Administration's size standards with total revenues of $13.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. The Secretary has determined that this final rule would have a significant economic impact on a substantial number of small entities. We define small HHAs as those with total revenues of $13.5 million or less in any 1 year. Analysis reveals a 2.62 percent decrease in estimated payments to small HHAs in CY 2012.

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

In this final rule, we have stated that our analysis reveals that nominal case-mix continues to grow under the HH PPS. Specifically, nominal case-mix has grown from the 17.45 percent growth identified in our analysis for CY 2011 rulemaking to 19.03 percent for this year's rulemaking (see further discussion in sections II.A. and II.B.). Nominal case-mix is an increase in case-mix that is not due to an increase in patient acuity. We believe it is appropriate to reduce the HH PPS rates to account for the increase in nominal case-mix, so as to move towards more accurate payment for the delivery of home health services. Our analysis shows that smaller HHAs are impacted slightly more than are larger HHAs by the provisions of this rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule applies only to HHAs. Therefore, the Secretary has determined that this final rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule is not anticipated to impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $136 million or more.

D. Detailed Economic Analysis

This final rule sets forth updates to the HH PPS rates contained in the CY 2011 HH PPS final rule. The impact analysis of this final rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based on Medicare claims from 2009. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to inaccuracies resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Comment: A commenter recommended that we modify our impact analysis approach. The commenter states that the proposed rule simply quantifies the percentage cut in rates on a geographic basis and broadly evaluates the impact of the changes on home health categories such as freestanding, hospital-based, nonprofits, and urban and rural providers.

Response: We believe that State-level impacts would be misleading unless we also provided break-outs of rural-verses-urban and ownership status of providers within the State. While we believe that our impact analysis is reflective of how HHAs are impacted by the provisions of this rule in that we provide impacts by type of facility, urban/rural, regions and other areas of the country, and facility size, we did perform a State-level analysis as the commenters suggested. That analysis shows similar results in that States estimated to see the more significant negative impacts, as a result of the provisions of this rule, are located in those areas of the country that are

estimated to see the most significant negative impact (that is, East South Central, West South Central, South Atlantic, East North Central, and Mountain). Analysis shows, for the States hit hardest in these areas of the country, not-for-profit HHAs and HHAs in rural areas are somewhat protected by provisions of this rule such as the redistributional effects of decreasing case-mix weights for high therapy cases and increasing case-mix weights for low and non-therapy cases, and the 3 percent rural add-on update.

In addition, for States in which significant negative impacts exist for non-profit and/or rural HHAs, we performed a preliminary analysis using 2009 freestanding Medicare cost report data (MCR). This analysis indicates a more than adequate volume of providers with margins strong enough to absorb the payment reductions to account for nominal case-mix growth. For example, our State-level analysis shows that Tennessee is the hardest hit State by the provisions of this rule, and is estimated to see a −6.18 percent decrease in payments from CY 2011 to CY 2012. While the impact on rural and not-for-profit HHAs in Tennessee is somewhat lessened for the reasons described above, they are still estimated to see significant decreases in payments in CY 2012. However, our preliminary analysis of 2009 freestanding MCR data indicate that Tennessee providers, including rural and not-for-profit HHAs, are experiencing margins which would enable them to absorb the reductions. Our analysis shows similar results in several other States in these areas of the country which are estimated to see relatively significant negative impacts as a result of the provisions of this rule. As such, since our analysis of freestanding HHA MCR data shows strong positive margins in these areas of the country, we believe that the provisions of this rule, should not lead to access to access to care issues. That being said, we would like to note that predicting agencies' margins (particularly, the increase in the number of agencies with negative margins) as a result of the provisions of this rule is difficult to do because many agencies may find ways to cut costs so that margins remain strong. This is supported by the fact that Medicare margins have remained strong since PPS implementation even with reductions in payments similar to the reduction being finalized in this final rule. We also understand that our analyses has limitations since it is based on 2009 MCR data, the latest complete MCR data at the time of preparation of this rulemaking. However, in their March 2011 Report to Congress, MedPAC projected an average of 14.5 percent margins for HHAs in 2011, when taking into account various payment adjustments such as the CY 2011 payment reduction for nominal case-mix growth.

To supplement the above described analysis, similar to analysis that we have performed in previous rulemaking when the issue of ''access to care'' was a concern, we also looked at estimated margins of HHAs, by county after estimating the impact of the provisions of this rule. We performed this analysis for the purposes of possibly identifying potential access risks associated with this rule. In particular, we looked to identify whether the finalized policies of this rule might increase the number of counties not served by at least one HHA with a positive margin. The analysis demonstrated that the occurrence of such counties was very infrequent. Looking further, we also identified that the counties we identified as not having at least one HHA with a positive margin did have at least one HHA in a contiguous county with a positive margin, or at a minimum it was determined that the provisions of this rule did not create a scenario where, for a county without at least one HHA with a positive margin, that county did not have a contiguous county with at least one HHA with a positive margin.

As we have previously described, our preliminary analyses indicate HH industry margins are sufficient to support a rate reduction of this size. We note that margin analysis alone is not an accurate access to care indicator. Many factors affect whether agencies with low or negative margin would close or not, such as the organization's mission, the availability of alternate sources of funding, and whether or not the organization is embedded in a larger one. We would also like to note that the number of agencies continues to grow, totaling around 11,000 in 2010, a 65 percent increase since 2002 and that access to care was not found to be inadequate in 2002, when the number of agencies nationally was much lower than it is today. Thus, given these reasons along with our described analysis above we do not believe that the finalized policies in this rule should result in access to care issues. At the core of our policies is our objective to pay appropriately for the efficient delivery of reasonable and necessary home health services. As always, we will, of course, continue to monitor for unintended consequences of the final policies of this rule.

Table 26 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule. For this analysis, we used linked home health claims and OASIS assessments; the claims represented a 20-percent sample of 60-day episodes occurring in CY 2009. The first column of Table 26 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the payment effects of the wage index only. The third column shows the payment effects of all the proposed policies outlined earlier in this rule. For CY 2012, the average impact for all HHAs due to the effects of the wage index is a 0.03 percent increase in payments. The overall impact for all HHAs, in estimated total payments from CY 2011 to CY 2012, is a decrease of approximately 2.31 percent.

As shown in Table 26, the combined effects of all of the changes vary by specific types of providers and by location. Rural and voluntary non-profit agencies fare considerably better than urban and proprietary agencies as a result of the proposed provisions of this rule. We believe this is due mainly to the distributional effects of the recalibration of the case-mix weights as described in section II.A of the proposed rule. Essentially, these impacts suggest that under the current case-mix system, rural and voluntary non-profit agencies bill less for high therapy episodes than do urban and proprietary agencies.

There is not much difference in the estimated impact (2.79 to 2.98 percent decreases) on HHAs when looking at the facility size based on the number of first episodes, with the lone exception being that the largest HHAs are estimated to see a 1.88 percent decrease in payments in CY 2012. There is considerable variation in the estimated impacts depending on the region of the country in which the HHA is located. HHAs in the North are estimated to see a 1.31 percent increase in payments while HHAs in other regions are estimated to receive between a 0.09 percent increase in payments (West) and a 3.83 percent decrease (South). HHAs in the New England, Mid Atlantic, and Pacific areas of the country are estimated to receive increases of 1.37 percent, 1.27 percent and 1.33 percent, respectively. However, HHAs in the South Atlantic, East South Central, West South Central, East North Central, West North Central, and Mountain areas of the country are estimated to receive decreases in payments ranging from 0.50 percent to 4.78 percent. Freestanding HHAs are estimated to see a 2.73 percent decrease in payments while facility-based HHAs

are estimated to see a 0.53 percent increase in payments. Voluntary not-for-profit HHAs are estimated to see a 0.52 percent increase in payments, while for-profit HHAs are estimated to see a 3.49 percent decrease in payments in CY 2012. Rural agencies are estimated to see a 1.52 percent decrease in payments in CY 2012, while urban agencies are estimated to see a 2.45 percent decrease in payments. Rural, freestanding, voluntary not-for-profit HHAs are estimated to see a 1.56 percent increase in payments. As described above, we believe the considerable variation in some of the estimated impacts is due mainly to the distributional effects of the recalibration of the case-mix weights.

BILLING CODE 4120–01–P

TABLE 26: Home Health Agency Policy Impacts for CY 2012, by Facility Type and Area of the Country

Group	Comparisons: Percent change due to the effects of the updated wage index (Percent)	Impact of all CY 2012 Policies[1] (Percent)
All Agencies	0.03	-2.31
Type of Facility		
Free-Standing/Other Vol/NP	0.20	0.30
Free-Standing/Other Proprietary	0.02	-3.51
Free-Standing/Other Government	-0.23	-1.33
Facility-Based Vol/NP	-0.09	0.87
Facility-Based Proprietary	-0.02	-1.88
Facility-Based Government	-0.12	0.05
Subtotal: Freestanding	0.05	-2.73
Subtotal: Facility-based	-0.09	0.53
Subtotal: Vol/NP	0.09	0.52
Subtotal: Proprietary	0.02	-3.49
Subtotal: Government	-0.17	-0.65
Type of Facility (Rural * Only)		
Free-Standing/Other Vol/NP	1.82	1.56
Free-Standing/Other Proprietary	0.13	-3.09
Free-Standing/Other Government	-0.28	-0.74
Facility-Based Vol/NP	-0.14	0.80
Facility-Based Proprietary	-0.29	-1.44
Facility-Based Government	-0.15	0.15
Type of Facility (Urban * Only)		
Free-Standing/Other Vol/NP	-0.04	0.11
Free-Standing/Other Proprietary	0.00	-3.58
Free-Standing/Other Government	-0.16	-2.13
Facility-Based Vol/NP	-0.07	0.90
Facility-Based Proprietary	0.17	-2.18
Facility-Based Government	-0.08	-0.06
Type of Facility (Urban* or Rural*)		
Rural	0.27	-1.52
Urban	-0.01	-2.45
Facility Location: Region*		
North	0.56	1.31

Group	Comparisons Percent change due to the effects of the updated wage index (Percent)	Impact of all CY 2012 Policies[1] (Percent)
South	-0.11	-3.83
Midwest	-0.28	-2.72
West	0.39	0.09
Outlying	0.23	-1.87
Facility Location: Area of the Country		
New England	1.23	1.37
Mid Atlantic	0.18	1.27
South Atlantic	-0.35	-3.94
East South Central	-0.63	-4.78
West South Central	0.31	-3.36
East North Central	-0.41	-3.21
West North Central	0.32	-0.50
Mountain	0.23	-2.71
Pacific	0.46	1.33
Outlying	0.23	-1.87
Facility Size: (Number of First Episodes)		
< 19	0.13	-2.93
20 to 49	0.15	-2.98
50 to 99	0.17	-2.80
100 to 199	0.05	-2.79
200 or More	-0.03	-1.88
Facility Size: (estimated total revenue)		
Small (estimated total revenue <= $13.5 million)	0.03	-2.62
Large (estimated total revenue > $13.5 million)	0.05	-0.92

Note: Based on a 20 percent sample of CY 2009 claims linked to OASIS assessments.
*Urban / rural status, for the purposes of these simulations, is based on the wage index on which episode payment is based. The wage index is based on the site of service of the beneficiary.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic**=Pennsylvania, New Jersey, New York; **South Atlantic**=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central**=Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central**=Alabama, Kentucky, Mississippi, Tennessee; **West North Central**=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central**=Arkansas, Louisiana, Oklahoma, Texas; **Mountain**=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific**=Alaska, California, Hawaii, Oregon, Washington; **Outlying**=Guam, Puerto Rico, Virgin Islands

[1] Percent change due to the effects of the updated wage index, the 1.4 percent proposed HH PPS payment update percentage, the 3.79 percent case-mix adjustment, and the 3 percent rural add-on.

BILLING CODE 4120–01–C

E. Alternatives Considered

As described in section V.C. above, implementing the case-mix adjustment for CY 2012 along with the HH PPS payment update percentage and the updated wage index, the aggregate impact would be a net decrease of $430 million in payments to HHAs, resulting from a $290 million increase due to the updated wage index and the HH PPS payment update percentage and a $720 million reduction from the 3.79 percent case-mix adjustment. If we were to not implement the case-mix adjustment for CY 2012, Medicare would pay an estimated $720 million more to HHAs in CY 2012, for a net increase in payments

to HHAs in CY 2012 of $290 million (HH PPS payment update percentage and updated wage index). We believe that not implementing a case-mix adjustment, and paying out an additional $720 million to HHAs when those additional payments are not reflective of HHAs treating sicker patients, would not be in line with the intent of the HH PPS, which is to pay accurately and appropriately for the delivery of home health services to Medicare beneficiaries. If we were to implement a 5.06 case-mix adjustment for CY 2012 along with the HH PPS payment update percentage and the updated wage index, the aggregate impact would be a net decrease of $670 million in payment to HHAs, resulting from a $290 million increase due to the updated wage index and the HH PPs payment update percentage and a $960 million reduction from a 5.06 percent case-mix adjustment. As we stated in our response to comments in Section II.A. of this rule, we are sensitive to the challenges HHAs may have had in adapting to the Affordable Care Act provisions which were implemented in CY 2011, such as the face-to-face encounter provision. We also agree that the Affordable Care Act provisions and the CY 2011 therapy changes described by commenters likely required HHAs to incorporate process changes to adhere to these new requirements. As such, we are finalizing a phased-in implementation of the 5.06 percent reduction over 2 years, as some commenters suggested. We believe that by phasing-in the reductions over CY 2012 and CY 2013, we allow HHAs an opportunity to adopt process efficiencies associated with the CY 2011 mandates prior to imposing the full 5.06 percent payment reduction.

Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions for nominal case-mix growth, changes in case-mix that are unrelated to actual changes in patient health status. We are committed to monitoring the accuracy of payments to HHAs, which includes the measurement of the increase in nominal case-mix, which is an increase in case-mix that is not due to patient acuity. As discussed in section II.A. of this rule, we have determined that there is a 19.03 percent nominal case-mix change from 2000 to 2009. To account for the remainder of the 19.03 percent residual increase in nominal case-mix beyond that which was has been accounted for in previous payment reductions (2.75 percent in CY 2008 through CY 2010 and 3.79 percent in CY 2011),), as described in the proposed rule and restated in Section II.A. of this rule, we have estimated that the percentage reduction to the national standardized 60-day episode rates for nominal case-mix change for CY 2012 would be 5.06 percent. As described in a comment and response in Section II.A. of this rule, commenters expressed concern that the proposed cut of 5.06 percent would impede access to home health care. Some commenters stated that rural areas would be hit the hardest by a case-mix reduction to payments. One commenter described his analysis which concluded that over 55 percent of agencies would be forced into negative margins as a result of the reductions. The commenter further stated that six States and Guam would have more than 70 percent of their agencies with negative margins in CY 2012 as a result of the proposed 5.06 percent reduction. In response to these comments, we noted that the effects of the payment update, the wage index update, and the revision of case-mix weights must also be taken into account when assessing the impact of a 5.06 percent reduction and that we believe the commenter did not do consider these in his analysis. We described our analysis which showed that the revision of the case-mix weights would have a re-distributional effect on HH PPS payments which benefit rural and non-profit HHAs, and HHAs in certain areas of the country. Our analysis showed that some rural and non-profit HHAs, as well as HHAs in certain areas of the country, were estimated to see an increase in payments in CY 2012, even with a 5.06 percent nominal case-mix reduction. We described our analysis of the combined effects of all the policies in the proposed rule, our preliminary analysis of Medicare CRs, and MedPAC's margin projections, and we concluded that Medicare margins are strong enough to absorb a 5.06 percent reduction to account for growth in nominal case-mix without impeding access. However, for the reasons described in section II.A. in this final rule, we are phasing-in the implementation of a 5.06 percent reduction over 2 years, finalizing a 3.79 percent reduction in CY 2012 and a 1.32 percent reduction in CY 2013.

We believe that the alternative of not implementing a case-mix adjustment to the payment system in CY 2012 to account for the increase in case-mix that is not real would be detrimental to the integrity of the PPS. As discussed in section II.A. of this rule, because nominal case-mix continues to grow (about 1 percent each year in 2006 and 2007, 4 percent in 2008, and 2 percent in 2009), and thus to date we have not accounted for all the increase in nominal case-mix growth, we believe it is appropriate to reduce HH PPS rates now, thereby paying more accurately for the delivery of home health services under the Medicare home health benefit. The other reduction to HH PPS payments, a 1.0 percentage point reduction to the proposed CY 2012 home health market basket update, is discussed in this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi) of the Act (as amended by the Affordable Care Act).

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 27, we have prepared an accounting statement showing the classification of the transfers associated with the provisions of this final rule. This table provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this final rule.

TABLE 27: Accounting Statement: Classification of Estimated Transfers, from the CY 2011 HH PPS to the CY 2012 HH PPS

Category	Transfers
Annualized Monetized Transfers	-$430 million
From Whom to Whom?	Federal Government to HH providers

G. Conclusion

In conclusion, we estimate that the net impact of the proposals in this rule is approximately $430 million in CY 2012 savings. The $430 million impact to the final CY 2012 HH PPS reflects the distributional effects of an updated wage index ($10 million increase), the 1.4 percent HH PPS payment update

percentage ($280 million increase), and the 3.79 percent case-mix adjustment applicable to the national standardized 60-day episode rates ($720 million decrease). This analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

V. Federalism Analysis

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

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

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

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

Subpart E—Home Health Services Under Hospital Insurance

■ 2. Section 409.42 is amended by revising paragraph (c)(4) to read as follows:

§ 409.42 Beneficiary qualifications for coverage of services.

* * * * *

(c) * * *

(4) Occupational therapy services in the current and subsequent certification periods (subsequent adjacent episodes) that meet the requirements of § 409.44(c) initially qualify for home health coverage as a dependent service as defined in § 409.45(d) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period. Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) are considered to be qualifying services.

* * * * *

■ 3. Section 409.44 is amended by revising paragraphs (c) introductory text, (c)(2)(i)(C)(*2*), and (c)(2)(i)(D)(*2*) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

(c) *Physical therapy, speech-language pathology services, and occupational therapy.* To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) and (2) of this section.

* * * * *

(2) * * *

(i) * * *

(C) * * *

(*2*) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide all of the therapy services and functionally reassess the patient in accordance with paragraph (c)(2)(i)(A) of this section during the visit associated with that discipline which is scheduled to occur close to the 14th Medicare-covered therapy visit, but no later than the 13th Medicare-covered therapy visit.

(D) * * *

(*2*) Where more than one discipline of therapy is being provided, the qualified therapist from each discipline must provide all of the therapy services and functionally reassess the patient in accordance with paragraph (c)(2)(i)(A) of this section during the visit associated with that discipline which is scheduled to occur close to the 20th Medicare-covered therapy visit, but no later than the 19th Medicare-covered therapy visit.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

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

Subpart B—Certification and Plan Requirements

■ 5. Section 424.22 is amended by revising paragraphs (a)(1)(v) introductory text and (a)(1)(v)(A) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(a) * * *

(1) * * *

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter, respectively. The face-to-face encounter must be performed by the certifying physician himself or herself, by a nurse practitioner, a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, a certified nurse midwife (as defined in section 1861(gg)of the Act) as authorized by State law, a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician, or, for patients admitted to home health immediately after an acute or post-acute stay, the physician who cared for the patient in an acute or post-acute facility and who has privileges at the facility. The documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled, dated and signed by the certifying physician.

(A) If the certifying physician does not perform the face-to-face encounter himself or herself, the nonphysician practitioner or the physician who cared for the patient in an acute or post-acute facility performing the face-to-face encounter must communicate the clinical findings of that face-to-face patient encounter to such certifying physician.

* * * * *

PART 484—HOME HEALTH SERVICES

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

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

Subpart E—Prospective Payment System for Home Health Agencies

■ 7. Section 484.250 is revised to read as follows:

§ 484.250 Patient assessment data.

(a) *Data submission.* An HHA must submit the following data to CMS:

(1) The OASIS–C data described at § 484.55(b)(1) of this part for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235 of this subpart, and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

(2) The Home Health Care CAHPS survey data for CMS to administer the payment rate methodologies described in § 484.225(i) of this subpart, and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

(b) *Patient count.* An HHA that has less than 60 eligible unique HHCAHPS patients annually must annually submit to CMS their total HHCAHPS patient count to CMS to be exempt from the HHCAHPS reporting requirements for a calendar year period.

(c) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS Survey on its behalf.

(1) CMS approves an HHCAHPS survey vendor if such applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(i) For HHCAHPS, a ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(ii) All applicants that meet these requirements will be approved by CMS.

(2) No organization, firm, or business that owns, operates, or provides staffing for a HHA is permitted to administer its own Home Health Care CAHPS (HHCAHPS) Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations will not be approved by CMS as HHCAHPS survey vendors.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: October 13, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 25, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–28416 Filed 10–31–11; 4:15 pm]

BILLING CODE 4120–01–P