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Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2010; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, and 484

[CMS–1560–F]

RIN 0938–AP55

Medicare Program; Home Health Prospective Payment System; Rate Update for Calendar Year 2010

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

ACTION: Final rule.

SUMMARY: This final rule sets forth an update to the Home Health Prospective Payment System (HH PPS) rates; the national standardized 60-day episode rates, the national per-visit rates, the non-routine medical supply (NRS) conversion factors, and the low utilization payment amount (LUPA) add-on payment amounts, under the Medicare prospective payment system for home health agencies effective January 1, 2010. This rule also updates the wage index used under the HH PPS. In addition, this rule changes the HH PPS outlier policy, requires the submission of OASIS data as a condition for payment under the HH PPS, implements a revised Outcome and Assessment Information Set (OASIS–C) for episodes beginning on or after January 1, 2010, and implements a Consumer Assessment of Healthcare Providers and Systems (CAHPS) Home Health Care Survey (HHCAHPS) affecting payment to HHAs beginning in CY 2012. Also, this rule makes payment safeguards that will improve our enrollment process, improve the quality of care that Medicare beneficiaries receive from HHAs, and reduce the Medicare program's vulnerability to fraud. This rule also adds clarifying language to the ''skilled services'' section and Conditions of Participation (CoP) section of our regulations. This rule also clarifies the coverage of routine medical supplies under the HH PPS.

DATES: *Effective Date:* These regulations are effective on January 1, 2010.

FOR FURTHER INFORMATION CONTACT:
Randy Throndset, (410) 786–0131 (overall HH PPS).
James Bossenmeyer, (410) 786–9317 (for information related to payment safeguards).
Doug Brown, (410) 786–0028 (for quality issues).
Kathleen Walch, (410) 786–7970 (for skilled services requirements and clinical issues).

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I. Background

A. Requirements of the Balanced Budget Act of 1997 for Establishing the Prospective Payment System for Home Health Services

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) enacted on August 5, 1997, significantly changed the way Medicare pays for Medicare home health 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 cost-based reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health 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 home health services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires that: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate 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 home health 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 that adjusts 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 home health services furnished in a geographic area compared to the applicable national average level. Pursuant to 1895(b)(4)(c), 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. Total outlier payments in a given fiscal year (FY) or year may not exceed 5 percent of total payments projected or estimated.

In accordance with the statute, we published a final rule (65 FR 41128) in the **Federal Register** on July 3, 2000, to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as

subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277), enacted on October 21, 1998; and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113), enacted on November 29, 1999. The requirements include the implementation of a HH PPS for home health 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 home health 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).

B. Deficit Reduction Act of 2005

On February 8, 2006, the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) was enacted. Section 5201 of the DRA requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to payment. This requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase will be reduced 2 percentage points. In accordance with the statute, we published a final rule (71 FR 65884, 65935) in the **Federal Register** on November 9, 2006 to implement the pay-for-reporting requirement of the DRA, codified at 42 CFR 484.225(h) and (i).

C. 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 home health disciplines (skilled nursing, home health 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 III.C.4.e). Durable medical equipment covered under the home health benefit is paid for outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument.

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

D. Corrections

We published a final rule with comment period in the **Federal Register** on August 29, 2007 (72 FR 49762) that set forth a refinement and rate update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for home health services for CY 2008. In this final rule with comment period, in Table 10B (72 FR 49854), the short description for ICD–9–CM code 250.8x & 707.10–707.9 should read ''PRIMARY DIAGNOSIS = 250.8x AND FIRST OTHER DIAGNOSIS =707.10–707.9. Instead of a formal correction notice, we are notifying the public of this correction in this final rule.

E. 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**. Most recently, we published a notice in the **Federal Register** on November 3, 2008 (73 FR 65351) 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 home health services for CY 2009.

F. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the August 13, 2009 proposed rule (74 FR 40948). In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Summary of the Proposed Provisions and Response to Comments

In the, August 13, 2009 **Federal Register** (74 FR 40948) we published the proposed rule entitled, ''Medicare Program; Home Health Prospective Payment System Rate Update for CY 2010'' and provided for a 60-day comment period. In this proposed rule we proposed updates to the Home Health Prospective Payment System (HH PPS) rates; the national standardized 60-day episode rates, the national per-visit rates, the non-routine medical supply (NRS) conversion factor, and the low utilization payment amount (LUPA) add-on payment amount, under the Medicare prospective payment system for home health agencies effective January 1, 2010. As part of the CY 2010 proposed rule (74 FR 40948), we also proposed a change to the HH PPS outlier policy, proposed to require the submission of OASIS data as a condition for payment under the HH PPS, and proposed payment safeguards that would improve our enrollment process, improve the quality of care that Medicare beneficiaries receive from HHAs, and reduce the Medicare program's vulnerability to fraud. The CY 2010 proposed rule also added clarifying language to the ''skilled services'' section and the Conditions of Participation (CoPs) sections of our regulations, and also clarified the coverage of routine medical supplies under the HH PPS. We also solicited comments on: Physician/patient interaction associated with the home health plan of care (POC); a Consumer Assessment of Healthcare Providers and Systems (CAHPS) Home Health Care Survey; the Outcome and Assessment Information Set (OASIS), Version C, effective January 1, 2010; proposed pay for reporting measures for use in CY 2011; and a number of minor payment-related issues. We also responded, in the CY 2010 proposed rule (74 FR 40948), to comments received as a result of our solicitation in the CY 2008 HH

PPS final rule with comment period (72 FR 49762).

In response to the publication of the CY 2010 HH PPS proposed rule, we received approximately 73 items of correspondence from the public. We received numerous comments from various trade associations and major health-related organizations. Comments also originated from HHAs, hospitals, other providers, suppliers, practitioners, advocacy groups, consulting firms, and private citizens. The following discussion, arranged by subject area, includes our responses to the comments and, where appropriate, a brief summary as to whether or not we are implementing the proposed provision or some variation thereof.

A. Outlier Policy

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the regular 60-day case-mix and wage-adjusted episode payment amount in the case of episodes that incur unusually high costs due to patient home health care needs. This section further stipulates that total outlier payments in a given year may not exceed 5 percent of total projected or estimated HH PPS payments. Section 1895(b)(3)(C) of the Act stipulates that the standard episode payment be reduced by such a proportion to account for the aggregate increase in payments resulting from outlier payments. Under the HH PPS, outlier payments are made for episodes for which the estimated cost exceeds a threshold amount. The wage adjusted fixed dollar loss (FDL) amount represents the amount of loss that an agency must bear before an episodes becomes eligible for outlier payments.

In recent years, our analysis has revealed excessive growth in outlier payments, primarily the result of suspiciously high outlier payments in a few discrete areas of the country. In our CY 2009 payment update, we did not raise the FDL ratio, given the statistical outlier data anomalies that we identified in certain targeted areas, because program integrity efforts, such as payment suspensions for HHAs with questionable outlier billing activities, were underway to address excessive, suspicious outlier payments that were occurring in these areas. Instead, we maintained the then-current (CY 2008) FDL ratio of 0.89 in CY 2009 while actions to remedy inappropriate outlier payments in these target areas of the country were effectuated.

In our CY 2010 HH PPS proposed rule, we expanded our outlier analysis to assess the appropriateness of adopting a lower target percentage of outlier payments to total HH PPS payments. We performed an analysis of all providers who receive outlier payments, focusing our analysis on total HH PPS payments, total outlier payments, number of episodes, number of outlier episodes, and location of provider. Specifically, our analysis incorporated a 10 percent per-agency cap on outliers and looked at outlier payments as a percentage of total HH PPS payments with that 10 percent per-agency cap in place. That analysis revealed that with a 10 percent per-agency outlier cap in place, outlier dollars accounted for approximately 2.1 percent of total HH PPS payments. Additionally, we performed a separate analysis on CMS data using Medicare provider numbers of members of a major association of home health agencies who claim to be safety-net providers, serving sicker, more costly patients. The average outlier payment to these agencies was found to be less than 2 percent.

In the proposed rule we recognized that although program integrity efforts associated with excessive outlier payments continue in targeted areas of the country, we continue to be at risk of exceeding the 5 percent statutory limit on estimated outlier expenditures. Therefore, we focused our analysis on whether a broader policy change to our outlier payment policy might also be warranted, to mitigate possible billing vulnerabilities associated with excessive outlier payments, and to adhere to our statutory limit on outlier payments. Our analysis revealed that a 10 percent per-agency cap in outlier payments would mitigate potential inappropriate outlier billing vulnerabilities while minimizing the access to care risk for high needs patients.

Therefore, to mitigate possible billing vulnerabilities associated with excessive outlier payments, and to adhere to our statutory limit on outlier payments, we proposed to implement an agency level outlier cap such that in any given calendar year, an individual HHA would receive no more than 10 percent of its total HH PPS payments in outlier payments. Additionally, we proposed to reduce the FDL ratio to 0.67 for CY 2010. This combination of a 10 percent agency level outlier cap, and reduced FDL ratio of 0.67, and allowing for future growth in outlier payments, resulted in a projected target outlier payment outlay of approximately 2.5 percent of total HH PPS payments in outlier payments.

Currently, we reduce the national standardized 60-day episode payment rates, the national per-visit rates, the LUPA add-on amount, and the NRS conversion factor by 5 percent in order to create an outlier pool that accommodates estimated outlier payments of 5 percent of total HH PPS payments. Targeting the percentage of outlier payments at approximately 2.5 percent would allow us to create a smaller outlier pool and return the remaining 2.5 percent to the HH PPS rates. In the proposed rule, we proposed to retain a 2.5 percent reduction to the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor to fund the proposed target of approximately 2.5 percent of total estimated HH PPS payments in outlier payments, adhering to the statutory requirement in section 1895(b)(3) of the Act.

Comment: Most commenters were very supportive, and in favor of the overall proposed HH PPS outlier policy. Commenters stated that anomalous outlier trends in recent years are compelling evidence that abusive and possibly fraudulent practices are widespread in many areas of the country and that increased safeguards are necessary to curb inappropriate activity as it relates to the billing of outlier episodes under the HH PPS. Commenters further stated that the proposed changes were reasonable areas of focus for additional safeguards against fraud and abuse in the area of billing for outliers in the HH PPS. Other commenters stated that they strongly supported CMS in its efforts to curb fraud and abuse and are not opposed to the proposed implementation of these changes to the outlier policy. Several commenters found the proposed outlier policy to be fair and expect the policy to be effective.

Response: We appreciate the overwhelming support from commenters that we received on our proposed HH PPS outlier policy. We would like to point out that fraudulent activity is not widespread in many areas of the country. These sort of fraudulent activities are occurring in a few discrete areas of the country. We continue to believe that an agency-level outlier cap is the appropriate policy, at this time, to mitigate possible billing vulnerabilities associated with excessive outlier payments and to adhere to our statutory limit on outlier payments. As such, in conjunction with the 10 percent agency level outlier policy, we proposed to target a new 2.5 percent outlier pool (as opposed to the existing 5 percent outlier pool), and return 2.5 percent back into the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor,

with a 0.67 FDL ratio. For reasons outlined later in this final rule, we are finalizing this outlier policy for CY 2010 only.

Comment: Several commenters supported the new, lower, outlier target of approximately 2.5 percent, and applauded CMS for restoring dollars to the HH PPS payment rates. A commenter commended CMS for thoughtfully considering the negative impact on patient access, should outlier payments be completely eliminated. A few commenters urged CMS to monitor outlier expenditures and further reduce the FDL if outlier payments drop below the new 2.5 percent target. A commenter asked CMS to explain the methods that would be used to monitor these outlier payments.

Response: We appreciate the support of the proposed outlier target of approximately 2.5 percent and returning 2.5 percent back into the HH PPS rates. As a commenter stated, CMS did give thoughtful consideration to eliminating the outlier policy altogether, and although we reserve the right to eliminate the outlier policy in the future, should circumstances make that necessary, we believe that an outlier target of approximately 2.5 percent and returning 2.5 percent back into the HH PPS rates, for CY 2010, is the appropriate policy at this time. As part of our final outlier policy, in addition to returning 2.5 percent back into the HH PPS rates, because of the 10 percent cap on outlier payments, CMS is also lowering the FDL from 0.89 to 0.67, making it easier for episodes to qualify for outlier payments. Thus, in addition to the fact that few non-fraudulent providers are expected to be impacted by the 10 percent cap, all providers will benefit from the 2.5 percent increase in the base rate and will also be helped by the lowering of the FDL ratio. As stated above, CMS plans to analyze overall national spending on outlier payments relative to the new 2.5 percent outlier pool by geographic area and provider type. CMS also plans on looking at outlier payments, per HHA, relative to the 10 percent cap on outlier payments at the agency level by geographic area and provider type.

Comment: There was a commenter who was opposed to returning a portion of the current 5 percent pool to the HH PPS rates, stating that doing so would reduce resources to provide for sicker patients and increase funds paid for lost-cost/low-utilization patients who are already well provided for. Another commenter was concerned about reducing the outlier pool to 2.5 percent, stating that it would hurt providers that accept difficult and hard-to-place patients.

Response: For the past several years, CMS has updated the FDL ratio in attempts to estimate outlier dollars to be no more than 5 percent. However, because outlier payments in certain areas of the country continue to increase at alarming rates, updating the FDL on an annual basis has proven to not be enough to keep outlier dollars at no more than 5 percent of total HH PPS payments. As we described in the proposed rule, our analyses show that when we remove from our analyses HHAs in areas of the country with high suspect outlier payments, as well as small agencies that are not representative of the types of agencies we suspect of suspicious billing activities, outlier payments for the rest of the country account for less than 2 percent of total HH PPS payments. As described in the proposed rule, our analyses have shown that in simulating payment for CY 2010, imposing an outlier cap of 10 percent at the agency level, we would pay approximately 2.32 percent of total HH PPS payments in outlier payments.

Additionally, in our separate analysis of CMS data using provider numbers from a major home health agency association's agencies, which claim to service a sicker, more costly population, only one of these agencies was estimated to exceed a 10 percent outlier cap. Further analysis shows us that approximately 70 percent of all HHAs receive between 0 percent and 1 percent in outlier dollars as a percentage of their total HH PPS payments. Consequently, we believe that a final outlier policy for CY 2010 that includes a 10 percent agency level outlier cap, a target of approximately 2.5 percent for outlier dollars as a percentage of total HH PPS payments, returning 2.5 percent back into the HH PPS rates, and a 0.67 FDL ratio is the appropriate policy, and that it appropriately pays for legitimate outlier episodes as well as all other types of episodes under the HH PPS. Because our trend analysis shows that outlier expenditures continue to grow, we proposed and are finalizing as part of our final outlier policy, an outlier target of approximately 2.5 percent.

Comment: Most commenters were in support of lowering the FDL ratio to that of 0.67, but urged CMS to carefully monitor the effects of reducing the FDL ratio to gauge whether there is an increase in inappropriate outliers and if increasing the FDL ratio might be necessary in the future. A commenter asked CMS to keep the FDL ratio at 0.89 because lowering it to 0.67 would make it easier for episodes to become outliers, thereby making it difficult for HHAs that are trying to stay under a 10 percent cap to meet the requirement and still deliver care. Another commenter stated that the proposal to reduce the FDL to 0.67, which would increase the number of episodes that qualify for outlier payments, is a ''futile gesture'' in the face of a 10 percent cap.

Response: We appreciate commenters' support of lowering the FDL ratio to 0.67. As stated above, CMS plans to analyze overall national spending on outlier payments relative to the new 2.5 percent outlier pool by geographic area and provider type. CMS also plans on looking at outlier payments per HHA relative to the 10 percent cap on outlier payments at the agency level by geographic area and provider type. At the same time, we will be looking at how the FDL ratio of 0.67 affects the percentage of outliers, and consider adjustments to the FDL ratio (up or down) if appropriate. We are decreasing the FDL ratio from 0.89 to 0.67 because the latest data and best analysis available tell us that in conjunction with an outlier policy that invokes a 10 percent agency level outlier cap and a target outlier pool of approximately 2.5 percent (returning 2.5 percent to the HH PPS rates), a FDL ratio of 0.67 is appropriate. As we stated in the proposed rule and throughout this final rule, if we are unable to see measurable improvements with respect to suspected fraudulent billing practices as they relate to HHA outlier payments, CMS may consider eliminating the outlier policy entirely in future rulemaking.

Comment: A number of commenters supported the ''rolling basis'' in determining whether outlier payments should be made at any given time during the year. However, another commenter cautioned CMS not to create a tracking nightmare for fiscal intermediaries and providers that is overly burdensome or complicated to administer. Yet another commenter was concerned about a delay in payments to HHAs, for services that have already been provided, and expenses that have already been incurred. That same commenter suggested that to address cash flow issues, CMS should delay the process of identifying and withholding outlier payments until the end of the first or second quarter of the calendar year, making it easier to HHAs to absorb early outlier cases. Another commenter was concerned that the ''rolling cap'' would result in accounting challenges, and suggested a quarterly look-back with a lump sum whenever outlier payments exceeded the 10 percent cap. A commenter stated that a rolling method could create excessive outlier

down-scores until the next calculation. The commenter believed that a retrospective adjustment would be fairer and would enable HHAs to reconcile revenue. Another commenter expressed concern about a retrospective recoupment, particularly an annual one, and the impact such a recoupment could have on the cash flow of smaller agencies and agencies with lower Medicare margins.

Response: Implementing the cap by a post-payment recoupment process, either quarterly or annual, would delay impact of the cap on HHAs that are billing outlier episodes inappropriately. Under a lump sum recoupment, there could be a total disruption to an HHA's cash flow. That is, if the amount of outlier dollars paid in excess of the cap and scheduled for recoupment is greater than the amount due to the HHA for other claims, the HHA's payment could stop completely for a time while the recoupment was made. We believe this sort of payment disruption is undesirable.

Under our planned implementation approach, for each home health provider, the claims processing system will maintain a running tally of the year-to-date (YTD) total home health payments. The claims processing system will ensure that each time an outlier claim for an agency is processed, actual outlier payments will never exceed 10 percent of the agency's YTD total payments. While an agency will always receive its base episode payment timely, the outlier portion of the claim will be paid on a rolling basis, as the agency's YTD payments support payment of the outlier. We plan to have a periodic reconciliation process under which outlier payments that were withheld are subsequently paid if the HHA's total payments have increased to the point that their outlier payments can be made. This reconciliation process will always result in additional cash flow to HHAs, and so we believe it is preferable. With regard to revenue tracking, distinct coding will be used on the HHA's remittance advice when outlier payments are withheld, assisting receivables accountants to identify and account for the differences between expected and actual payments. For these reasons, we agree with the commenter that supported a rolling implementation of the cap and will finalize this proposal.

Comment: A number of commenters encouraged CMS to take more aggressive actions through program integrity activities. One commenter recommended that a high rate of outliers for a particular HHA should trigger medical review, creating a greater/more effective deterrent to fraudulent behavior. In general, the commenter supported more aggressive enforcement. A commenter stated that reference areas with fraud should have much higher incidence of additional document requests (ADRs) and phone calls to beneficiaries from fiscal intermediaries. Documentation should be closely reviewed for medical necessity, qualifications, and homebound status.

Response: As we stated in the proposed rule, so far as activities related to high levels of suspicious outlier payments, CMS is continuing with program integrity efforts including possible payment suspensions for HHAs with questionable outlier billing activities.

Comment: Commenters asked that CMS clarify that while outlier payments would be capped at 10 percent, at the agency level, that the non-outlier portion of the payment would still be paid.

Response: We thank the commenters for this comment, and apologize if we were not clear as to what portion of the HH PPS payment would be subject to the 10 percent cap. As stated in the proposed rule (at 74 FR 40957),the outlier policy, finalized for CY 2010 only, will include a 10 percent cap on outlier payments at the agency level. That is to say, an agency's outlier payments are to be capped at 10 percent of its total HH PPS payments (of which outlier payments are a part). For any claim with an outlier payment, if it were determined that paying the outlier portion of the total HH PPS payment for that claim would result in the HHA exceeding the 10 percent cap in outlier payments, only the outlier portion of the claim would not be paid at that time. However, the regular HH PPS payment (based on the HHRG that applies to that claim) is not subject to that 10 percent outlier cap, and thus would be paid. Any HH PPS payment adjustments other than the outlier payment (that is, PEP, recoding for therapy visits, *etc.*), would also continue to apply to the claim.

Comment: CMS' analysis in the proposed rule started by first identifying ''all providers who receive outlier payments'' but excluded agencies with greater than 15 percent outlier episodes for one reason or another. Such exclusion skews analysis in favor of the 10 percent cap at the agency level, without considering that HHAs are shouldering the burden of serving sicker, more costly patients, represented by the excluded agencies with greater than 15 percent outlier episodes.

Response: The purpose of our analyses was to show the impact of the outlier cap policy on agencies not likely to be receiving inappropriate outlier payments. It is clear that a 10 percent agency outlier cap would have a major effect on agencies in certain areas of the country involved in suspect inappropriate billing practices. As such, we did not want to have data from those agencies skewing the results. To clarify, we did not exclude agencies with either outlier payments or outlier episodes greater than 15 percent. We did exclude agencies from our analysis that received sizeable outlier payments (totaling at least $100,000), had high ratio of outlier payments to total HH PPS payments (30 percent or more), and were located in the counties in Florida, Texas and California where program integrity issues had been identified. Those agencies simultaneously satisfying all three of these exclusion criteria were considered highly suspect for inappropriate billing practices. We also excluded a small number of agencies that had fewer than 20 Medicare HH PPS episodes, believing that Medicare beneficiaries account for such a small part of their business that they are not representative of the types of agencies we are most concerned about disadvantaging with an outlier cap policy. Finally, we excluded a few additional agencies because they, too, were located in those same counties experiencing program integrity issues, and thus we did not want to have data from those agencies skewing the results either.

Comment: Some commenters suggested that the proposed outlier policies will put small HHAs out of business, while larger HHAs will be impacted only slightly. A commenter suggested that small HHAs will have to transfer their complex patients to larger HHAs that generate enough income to receive outlier patients, leaving small HHAs with limited service offerings and more competitive disadvantages. The commenter further asked CMS to further research the impact that the 10 percent cap will have on HHAs that generate $2 million or less. Another commenter stated that special consideration should be given to smaller HHAs with fewer than 50 patients with low socioeconomic status (SES). The commenter also stated that CMS should take into account that there are cultural and racial reasons why certain areas may have more home health chronic patients. Another commenter stated that our proposed outlier policies would eliminate a safety net for HHAs that typically treat higher needs patients. Some commenters cautioned CMS to analyze carefully the effects of such an outlier policy to ensure that HHAs and

beneficiaries and rural and under-served areas are not adversely affected. A number of commenters urged CMS to ensure that HHAs that legitimately serve sicker/more clinically complex patients are not penalized or put out of business, causing access issues for beneficiaries. Another commenter suggested that in some areas lacking of other post acute settings available to beneficiaries, HHAs may have higher outlier costs. There was, however, a commenter who stated that the proposed outlier policy assumes some financial loss from outlier episodes, but that the commenter's analysis on freestanding HHAs indicates that some HHAs have lower costs than those costs assumed in the proposed policy. Consequently, these HHAs with lower costs may be able to profit from abusing the outlier policy, even with a smaller outlier pool and provider level cap.

Response: Our analysis (see proposed rule at 74 FR 40956) shows that when the counties with program integrity problems are removed, the vast majority of the remaining providers have outlier dollars below 10% of their total home health expenditures and thus will not be affected by the policy. Further mitigating the effects of the outlier policy is that the base rates for all episodes are being increased by 2.5%. An alternative, as was discussed in the proposed rule, would be to eliminate the outlier policy altogether, an option that some providers might find even less appealing. While we continue to believe that our proposed outlier policy would not negatively impact the access to home health care, we believe it prudent to carefully monitor the impact that this new policy may have on access to home health care. Therefore, we are finalizing our proposed outlier policy, but for CY 2010 only. We will closely monitor data trends and we may make this policy, or some variation of this policy, permanent in future rulemaking. We believe that a final outlier policy for CY 2010 that includes a 10 percent agency level outlier cap, a target of approximately 2.5 percent for outlier dollars as a percentage of total HH PPS payments, returning 2.5 percent back into the HH PPS rates, and a 0.67 FDL ratio is the appropriate policy at this time.

Comment: Some commenters opposed the proposed outlier policy, stating that it penalized HHAs that treat insulin-dependent diabetes mellitus (IDDM) patients. These commenters stated that this policy would ultimately end up causing patients with IDDM to be denied treatment, and thus jeopardizing their lives. The same commenter stated that IDDM patients have always been the exception to the rule, ''end in sight''. The commenter went on to say that this policy would be life threatening to insulin dependent diabetics because they would have no one to administer their insulin. The commenter stated that they were one of the few HHAs that accepted these types of patients, and that if the 10 percent outlier cap were implemented, there would be no HHA to take these patients, resulting in insulin mismanagement, increased hospitalizations, and complications (including death). The commenter stated that Houston has a high population of IDDM patients, and that CMS should consider regions/geography as to how an outlier cap should appropriately be applied.

A few commenters wanted to see exceptions for certain types of patients, while other commenters wanted to see exceptions for HHAs specializing in treating certain types of patients. One commenter proposed that HHAs specializing in chronic disease management (diabetes, congestive heart failure (CHF), wound care, etc.), with criteria to safeguard against fraud, should be exempt from the 10 percent outlier cap policy. The commenter stated that criteria may include having specialty providers working with the HHA and that enhanced services (placing the patient as an outlier) are necessary. The commenter pointed out that, in their State, an association of diabetes educators was working towards being able to certify HHAs with a ''Diabetes Education Program'' which could also be a requirement for those with outlier diabetics. HHAs providing that specialty care should be willing to collect and report data on outcomes to assure quality care is being provided. A commenter stated that while a 10 percent outlier cap may be appropriate in most cases, episodes in which IDDM patients are being served should be exempt from that policy. Another commenter suggested that an exemption for those HHAs willing to follow criteria for specialty care to safeguard against fraud should be excluded from the cap.

Another commenter adamantly opposed the 10 percent outlier cap, as they specialize in diabetic care, and such a policy would affect the way they do business and their cash flow. The commenter stated that they would be forced to transfer IDDM patients to other HHAs. The commenter stated that such patients should not be punished by forcing them to change providers due to government policy rather than choice. The commenter also suggested that CMS do more research on the impact of such a change and the effects that such a change would have on competitive dynamics as well as ways to ''even the playing field.'' Another commenter suggested that CMS allow higher cap percentages for counties with high IDDM populations.

Another commenter was opposed to the 10 percent outlier cap, stating that it would put their patients in jeopardy. The commenter went on to say that they see elderly and mentally disabled adults through Diabetic Outreach Services (DOS). The commenter stated that many patients in DOS have vision disturbances, cognitive impairment, or dexterity issues and are on the Medicare home health benefit for multiple daily insulin injections. Without the HHA, or a willing/able caregiver, these patients would likely dose incorrectly or not at all, leading to hospitalization, SNF placement, or death. The commenter further stated that those IDDM patients receiving services from home health agencies have fewer hospitalizations or urgent use of the medical system.

A few commenters were opposed to the proposed outlier policy, stating that they take the ''difficult cases'' such as the unwanted children with psychiatric issues, low SES, IV, wound-care, and other diabetic cases, many of whom do not have caregivers. Many of their homebound patients are also vision impaired, have dexterity issues, or have dementia and/or Alzheimer's disease and require someone to be involved in their care. Those in assisted living facilities have even more specialized needs. The commenter stated that assisted living facilities are not always able to check glucose levels, and some are prohibited from administering insulin. The commenter stated that many patients cannot administer insulin safely, and families are unable to do so due to work schedules. The commenter wrote that incorrectly administered insulin can cause frequent calls to 911 and visits to the emergency room, and that poorly managed diabetes can cause hyperglycemia, hypoglycemia, and death. The commenter stated that if this outlier policy were to be implemented, their patients would end up in the hospital, only redirecting Medicare costs to high hospital bills. The commenter went on to say that their agency sees patients in the homes and assisted living facilities for ''house call'' diabetic services, and that patients who are homebound and residing in assisted living facilities would be adversely affected by this proposal. The commenter stated that putting a cap on outliers will force HHAs to ''dump'' IDDM patients, causing concern about these patients losing access to quality care.

Response: Excessive billing for IDDM patients in counties with program

integrity concerns is one of the main reasons necessitating the new outlier policy. However, we are sensitive to the commenter's concerns that homebound IDDM patients receive diabetes management support; likewise, we are sensitive to the support and disease management needs of patients with chronic diseases such as other types of diabetes, CHF, and wound care. Under Medicare's home health benefit, agencies are expected to provide education and training to help IDDM (and other diabetic) patients self-manage their diabetes. Many homebound patients with diabetes require short-term management for skilled observation, assessment, teaching and training activities. If the patient is unable to learn to self-manage, including self-administer medication, the home health agency would be expected to provide the teaching and training to a care-giver or family member. There will always be a subgroup of patients who cannot learn self-management, do not have a willing and able caregiver, and/or have no community support. However, as discussed in the proposed rule, our analysis shows us that after excluding HHAs in certain areas of the country where fraudulent billing practices are suspected, we expect that less than 2 percent of all Medicare HHAs would be affected by a 10 percent cap on outlier payments, and that of that less than 2 percent of HHAs, almost all are located in urban areas where beneficiaries have other choices. We also expect that the ability of agencies to receive 10 percent of their total payment in outliers would partially compensate agencies for the care associated with this subgroup. The outlier policy in the HH PPS was never intended to fully compensate HHAs for episodes that incur unusually high costs due to patient home health care needs. Rather, the intent of the outlier policy is to mitigate the negative financial impact that unusually high cost patients have on HHAs. We believe that our final outlier policy for this rule, that includes a 10 percent per-agency cap on outlier payments, is consistent with that intent. Our analysis shows us that approximately 70 percent of HHAs receive between 0 percent and 1 percent in outlier payments. Therefore, we believe our final outlier policy (which includes a 10 percent cap on outlier payments at the agency level) is reasonable and responsible. We also encourage home health agencies to take advantage of the help and support available from organizations such as the American Diabetes Association, the Indian Health Service, and the American Association of Diabetic Educators regarding innovative techniques associated with diabetes self management training (DSMT). Collaborating with these organizations may allow agencies to achieve greater success in enabling IDDM patients and/or their caregivers to better achieve self-management, and may provide the agencies with innovative care suggestions regarding their IDDM patients. CMS will closely monitor utilization trends of IDDM home health patients to assess the impact this policy may have on their access to care. Specifically, we plan to look at pre-2010 data to analyze trends of home health usage by IDDM patients, looking also at patterns of their Medicare utilization prior to the home health episode, and will compare those patterns with current usage.

Comment: A commenter stated that while MedPac may have reported that beneficiaries have access to an adequate number of HHAs, the reality is that many HHAs limit acceptance of high-utilization patients due to lack of resources or to protect their bottom line. The commenter also stated that they accept referrals for patients that other agencies will not admit. Another commenter stated that they would not be able to accept these types of patients if the proposed outlier policy were implemented, stating that they already take a 20 percent loss on these patients, which they offset with the few low-utilization short episodes they receive. The commenter stated that their agency will be restricted in the number of high utilization, sicker patients that they will accept. The commenter stated that many HHAs will not gamble with reimbursement calculations, timing, and cash flow issues that would be associated with a 10 percent cap. Consequently, the commenter believed that there would be no agency for many of the patients to turn to, and therefore this would likely result in an access to care issue.

Response: While experience varies from year to year, on average, the increased cost of sicker patients should generally be offset by the decreased cost for other patients. As stated in an earlier response to comments, based on our analysis (which excludes HHAs in certain areas of the country involved in potentially fraudulent billing practices), we expect that less than 2 percent of all Medicare HHAs may be affected by a 10 percent cap on outlier payments, and of this group of HHAs who may be affected by the 10 percent outlier cap, a vast majority are located in urban areas where beneficiaries have other choices. That being stated, an overwhelming majority of HHAs will not be affected by the 10 percent outlier cap, and thus will be in a position to accept patients who legitimately need home health services, and meet the eligibility requirements for the Medicare home health benefit.

Comment: A few commenters generally supported the proposed outlier policy, but recommended modifications to the policy. Generally speaking, some commenters requested that an appeals process be created for HHAs that CMS initially determined to have exceeded the 10 percent cap. The concern here was that such a cap could potentially affect legitimate outlier cases. As such, a commenter stated that situations could evolve in which high needs patients receiving care at one HHA are forced to change agencies during a potentially critical time. This commenter also found it concerning that we would have a cap policy that could potentially not allow for reimbursement for a valid outlier case. Another commenter suggested that CMS target areas where the data indicate the overutilization of outliers, rather than applying the policy to all HHAs in the country. We also received the following recommended modifications: (1) The cap should be put in place no earlier than 2011 (different versions of a delay included that of a delay until it is clear that Congress has addressed the issue, while another version suggested phasing-in the 10 percent cap by starting with a higher cap of 15 or 20 percent); (2) CoPs should be amended to allow agencies to discharge outlier patients when it can be estimated that a HHA will exceed the cap; similarly, CoPs should be amended to permit a HHA to deny admission to an outlier patient when its estimated cap will be exceeded. CoP amendments should also address patient notice rights; (3) During pendency of cap discharges, allow an exception to the cap if a HHA can show that it took all reasonable measures to secure alternative care for qualified patients; (4) Establish an exemption if the provider exceeding cap can show that patients served are qualified and that no other HHA is available to admit them; (5) Establish a registry of HHAs that report availability to accept outlier patients; (6) Issue ''best-practice'' guidelines for dealing with outlier patients; (7) The Secretary of HHS should coordinate regulatory efforts with current proposals in Congress that would modify outlier standards. Not doing so could result in piecemeal enactment which could put HHAs at higher risk; (8) Clarify that the application of the cap calculation is based solely on outlier adjustments.

Response: An appeals process would be cumbersome and difficult to implement for such a small percentage of situations. HHAs should be able to predict whether they will be affected by a 10 percent outlier cap policy based on past utilization and, in legitimate situations, be able to point the beneficiaries to alternatives. CMS is moving forward with implementation of the 10 percent outlier cap for CY 2010, effective January 1, 2010. With suspect fraudulent outlier billing practices continuing to increase, we believe it crucial to implement this policy now (CY 2010) rather than delay. Additionally, a delay, while maintaining the current FDL ratio of 0.89, would not be possible. In such a scenario (that is, a delay), CMs would have to either eliminate the outlier pool altogether, or raise the FDL ratio significantly (see CY 2009 HH PPS Update Notice at 73 FR 65357), so as to maintain a 5 percent outlier pool, if the 10 percent outlier cap were not implemented this year. However, CMS does not believe that eliminating the outlier policy or raising the FDL ratio is the appropriate policy at this time. Revisions to existing CoPs do not need to take place in order to implement this outlier policy. CoPs do not, and are not intended to, address or restrict the ability of HHAs to discharge patients. The HHA is required to accept patients with a reasonable expectation that the patient's medical, nursing, and social needs can be adequately met by the agency at the patient's place of residence (42 CFR 484.18). The CoPs already address patients' rights at 42 CFR 484.10. Given the availability of HHAs, and the estimated infrequency of circumstances where legitimate cases might exist, we do not believe that exemptions are necessary. As noted in a previous response to comments, as stated in the proposed rule (at 74 FR 40957) and finalized in this rule for CY 2010 only, the outlier policy will include a 10 percent cap on outlier payments at the agency level. That is to say, an agency's outlier payments are to be capped at 10 percent of its total HH PPS payments (of which outlier payments are a component). For any claim with an outlier payment, if it is determined that paying the outlier portion of the total HH PPS payment for that claim would result in the HHA exceeding the 10 percent cap in outlier payments, the outlier portion of the claim would not be paid at that time. However, the regular HH PPS payment (based on the HHRG that applied to that claim) would not be subject to that 10 percent outlier cap, and thus would be paid. Any HH PPS payment adjustment (that is, PEP, recoding for therapy visits, *etc.*) other than the outlier payment, would also continue to apply to the claim.

Comment: A commenter agreed with the approach, but stated that the overarching problem is that beneficiary needs have increased and that the flaw is not in the outlier policy but in low reimbursement. The commenter suggested that CMS develop more accurate methods to deal with HHAs that ''gamed'' the outlier policy, versus putting forward the proposed policy. The commenter asked CMS to consider something akin to the hospice cap, but with a modifier to allow for HHAs with sicker patients.

Response: We disagree that the flaw is in the low reimbursement rates. The newly refined 153–HHRG case-mix model now reflects different resource costs for early home health episodes versus later home health episodes and expanded the case-mix variables included in the payment model. The newly refined model also replaced the previous single 10-therapy threshold with three therapy thresholds (6, 14, and 20 therapy visits), with gradual payment increases between the first and third therapy thresholds. The newly refined model also includes six severity levels at which it pays for non routine medical supplies (NRS). We believe that the new model has addressed the areas identified by the industry as ''not being accounted for'' in the previous 80–HHRG case-mix model. Sicker patients are accounted for in the more detailed 153–HHRG case-mix model. Home health margins, even by industry standards, have been generous.

Comment: Several commenters whose parents are Medicare HHA patients were opposed to the proposed outlier policy, stating that their parents are diabetic and unable to administer insulin; that the children's work schedules are not flexible, and consequently the adult children are not consistently available to assist their parents. These commenters stated that they rely on the HHA to administer the insulin to their parents. These commenters emphasized that their parents have paid into the Medicare program and that it should be available to them in their time of need. The commenters also stated that changing this would be a horrible burden on them, as they would have to have their parents move into their homes, which would be a difficult situation. Commenters stated that their parent's independence would be lost forever and that their overall health would suffer. These commenters stated that they may have to change jobs, which was not an option at this time; otherwise their parents would not get their insulin regularly. The commenters stated that if their parents would not move in with them, their parents would go into a nursing home. Commenters believed this was an attempt by CMS to save money while risking the lives of patients. These commenters urged CMS to reconsider the outlier policy. One commenter, an insulin patient, stated that he/she was unable to give himself/herself shots and did not have family to do so on a regular basis. The commenter went on to say that if nurses cannot come to their home, he/she would end up in the hospital or nursing facility. The commenter stated that the cost to be in a nursing facility would be more than the cost of a home health nurse who comes to his/her home. The commenter requested that CMS not change how it pays the home health nurse.

Response: CMS is sympathetic to the fact that some beneficiaries who need help administering insulin. The new outlier policy is intended to address the inappropriate, potentially fraudulent billing practices that we are seeing. In our view, there is no reason to expect a large number of insulin patients unable to treat themselves would all be utilizing a single provider, and this is, in fact, generally the case in all areas of the country except those with severe program integrity issues. We believe that by implementing such a policy, in conjunction with the continued program integrity efforts, including possible payment suspensions for HHAs with questionable outlier billing activities, Medicare beneficiaries will continue to receive the services they need, while providers receive appropriate payment for the services they provide. We are committed to addressing potentially fraudulent activities, especially those in areas where we see suspicious outlier payments, and will monitor and aggressively pursue actions towards agencies where inappropriate billing of outlier payments is identified.

Comment: One commenter urged CMS to re-examine the outlier policy in its entirety, as some HHRGs have more underlying cost variation than others. Another commenter recommended that CMS modify use of HHRG scores and related payment in PPS for diabetic episode and outlier payments, rather than limit the number of diabetic patients that an HHA can care for and be paid for. A commenter suggested we re-examine the outlier payment policy in its entirety. This commenter wrote that some HHRGs have significantly more underlying variation in costs than others. Additionally, he wrote that high therapy cases are unlikely to have

outliers because of therapy dominance. He added that agencies with a high proportion dual eligibles have different visit profiles due to the more acute needs of dual eligibles. This commenter believes that these issues suggest that a uniform fixed loss threshold and loss ratio across all HHRGs may not be appropriate policy. The commenter suggested that a more customized policy should be examined and may obviate the need for a cap altogether. Another commenter suggested that good HHAs may easily exceed the cap, but fraudulent HHAs may use outlier clients as a method of getting cross-referrals from other fraudulent HHAs for non-outlier patients. The commenter stated that the proposed policy will not eliminate fraud/abuse or save Medicare dollars because most outlier patients would be spread to all providers in an area. CMS would still be paying for just as many outlier cases, but they would be spread amongst more providers. The commenter suggested that a better approach would be to increase the FDL ratio so that estimated outlier dollars were close to the 5 percent allowed under statute. The commenter also suggested that another approach could be to cap payment based on the published per visit rates, multiplied by the number of visits billed, or the outlier payment, whichever is lower. Another commenter recommended grandfathering in current patients, as HHAs shouldn't abandon patients already receiving services. The commenter also recommended grandfathering in each HHA's current percentage of outliers and using that percentage as the cap for that HHA. A few commenters also suggested that in setting caps, CMS should consider the population of the county.

Response: The premise of the new outlier policy is not that the case-mix model is not accurately capturing the cost of resources in providing care for these patients. Rather, the new outlier policy is being implemented due to the frequency of inappropriate and possibly fraudulent billing practices. The commenter's suggestion of increasing the FDL to pay 5 percent in outlier dollars is precisely what CMS had been doing in past years, before the highly suspect, and possibly fraudulent, billing activities became so prevalent. As we stated in a previous response to comments, our analysis shows us that minus the suspect fraudulent activity, we believe that 2.5 percent is a more appropriate target for outlier payments as a percentage of total HH PPS payments. As such, we do not believe that simply increasing the FDL to pay outlier payments at 5 percent of total HH PPS payments is the appropriate policy at this time. Increasing the FDL ratio would prevent many legitimate outlier cases from being considered as such, essentially hurting the larger majority of HHAs that are billing appropriately. The commenter's suggestion that we pay HHAs the lower of the published per-visit rates multiplied by the number of visits billed, or the current calculated outlier payment, would not be an acceptable alternative, as the end result would be to pay the outlier payments as currently calculated. Using a HHA's current outlier percentage as the cap for that HHA would ignore the problematic billing that has been occurring, and would do nothing to control the problem that exists today with outliers in home health.

Comment: A commenter stated that there exist a number of negative effects, which are significant and should be modified/addressed, if the proposed outlier policy were implemented, which include: (1) Legitimate benefits would decrease due to lack of access resulting in a poorer quality of care due to the incentives to restrict care to diabetics to avoid outlier status; therefore, people would not receive care at home due to outlier status, resulting in an increase in the use of hospitals, nursing homes and emergency rooms; (2) Costs will increase; (3) Increasing number of patients will be displaced from homes, creating emotional and physical hardship on patients and families, yet patients respond best in a comfortable home environment; (4) It would be more cost-effective and promote better care if the HHA were to specialize in diabetic care, as long as such care was medically necessary and the patient was homebound.

Response: As stated in an earlier response to comments, based on our analysis (which excludes HHAs in certain areas of the country involved in suspicious billing practices), we expect that less than 2 percent of all Medicare HHAs will be affected by a 10 percent cap on outlier payments, and that of this group of HHAs who may be affected by the 10 percent outlier cap, a vast majority are located in urban areas where beneficiaries have other choices. Thus, an overwhelming majority of HHAs will not be affected by the 10 percent outlier cap, and will be in a position to accept patients who legitimately need these services, and meet the eligibility requirements for the Medicare home health benefit. As such, we do not believe that increased costs will occur as a result of increases in hospital or nursing home stays, or visits to emergency rooms.

To summarize, we believe that our final outlier policy, for CY 2010 only, that includes a 10 percent cap on outlier payments at the agency level, in concert with a new 2.5 percent outlier pool (as opposed to the existing 5 percent outlier pool), and returning 2.5 percent back into the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor, with a 0.67 FDL ratio, to be the appropriate policy at this time.

We will continue to monitor the trends in outlier payments and any related policy effects. Specifically, we plan to analyze overall national spending on outlier payments relative to the new 2.5 percent outlier pool by geographic area and provider type. We also plan to look at outlier payments, per HHA, relative to the 10 percent cap on outlier payments at the agency level by geographic area and provider type. So far as activities related to high suspect outlier payments, CMS is continuing with program integrity efforts including possible payment suspensions for suspect agencies. We will re-examine this policy in future rulemakings, and will consider further adjustments to this policy for CY 2011 and future years.

Implementation strategy for a 10 percent agency level cap on outlier payments.

CMS plans on implementing the 10 percent cap policy by making determinations as to whether or not a given outlier payment exceeds the 10 percent cap on a ''rolling'' basis. Under our planned implementation approach, for each home health provider, the claims processing system will maintain a running tally of the year-to-date (YTD) total home health payments. The claims processing system will ensure that each time an outlier claim for an agency is processed, actual outlier payments will never exceed 10 percent of the agency's YTD total payments. While an agency will always receive its base episode payment timely, the outlier portion of the claim will be paid as the agency's YTD payments support payment of the outlier. We plan to utilize a periodic reconciliation process under which outlier payments that were withheld are subsequently paid if the HHA's total payments have increased to the point that its outlier payments can be made. This reconciliation process will always result in additional cash flow to HHAs, and so we believe it is preferable. With regard to revenue tracking, distinct coding will be used on the HHA's remittance advice when outlier

payments are withheld, assisting receivables accountants in identifying and accounting for the differences between expected and actual payments.

B. Case-Mix Measurement Analysis

In the CY 2008 HH PPS final rule with comment period, we stated 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 nominal and real. As stated in the proposed rule, we have continued to monitor case-mix changes and our latest analysis supports the payment adjustments which we implemented in the CY 2008 HH PPS.

The case-mix analysis used for this rule uses PPS data from 2007. As discussed in the proposed rule, this analysis indicates a 15.03 percent increase in the overall observed case-mix since 2000. We next determined what portion of that increase was associated with a real change in the actual clinical condition of home health patients. As was done for the CY 2008 final rule, using Abt Associates' 6-phase model, we examined data on demographics, family support, pre-admission location, clinical severity, and non-home health Part A Medicare expenditure data to predict the average case-mix weight for 2007. Our best estimate is that approximately 9.77 percent of the 15.03 percent increase in the overall observed case-mix between the IPS baseline and 2007 is real; that is, due to actual changes in patient characteristics.

The estimate of real case-mix change continues to decrease for a number of reasons: First, because the nominal change in case-mix continues to grow, real case-mix as a percentage of the total change/increase in case-mix becomes less. With each successive sample, beginning with 2005 data (in the CY 2008 final rule), the predicted average national case-mix weight is moving very little because the variables in the model used to predict case-mix are not changing much. At the same time, the actual average case-mix continues to grow steadily. Thus, the gap between the predicted case-mix value, which is based on information external to the OASIS, and the actual case-mix value, grows with each successive sample. Consequently, as a result of this analysis, CMS recognizes that a 13.56 percent nominal increase ((15.03 − (15.03 × 0.0977)) in case-mix is due to changes in coding practices and documentation rather than to treatment of more resource-intensive patients.

We stated in our CY 2008 HH PPS proposed and final rules that we might find it necessary to adjust the offsets as new data became available. Given that we have adjusted the rates for two consecutive years by −2.75 percent in each year (2008 and 2009), based on 2007 data, if we were to account for the remainder of the 13.56 percent residual increase in nominal case-mix over the next two years, we estimate that the percentage reduction in the rates for nominal case-mix change for each of the remaining two calendar years (2010 and 2011) of the case-mix change adjustment would be 3.51 percent per year. If we were to account for the remaining residual increase in nominal case-mix in CY 2010, we estimate that the percentage reduction to the national standardized 60-day episode rates and the NRS conversion factor would be 6.89 percent. In the proposed rule, we proposed to move forward with our existing policy, as implemented in the August 22, 2007 CY 2008 final rule, of imposing a 2.75 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor for CY 2010. We stated that we would continue to monitor any future changes in case-mix as more current data became available and update as appropriate.

Comment: A number of commenters were opposed to further payment reductions based on estimates of nominal CM change. One commenter wrote that CMS assumes upcoding, yet 2008 HHA payments are $1 billion less than 1997 payments. Several commenters noted that HHAs have faced years of market basket update reductions during this decade, and that combined with annual wage index uncertainties and reform pending in Congress, and a case-mix adjustment on top of these other reductions, the survival of HHAs is threatened. The commenter stated that reductions may force the quality providers out of business, jeopardizing access, and leaving only those who ''game'' the system to provide care. A commenter wrote that this is contrary to the interests of Medicare's long term solvency or growing future care needs, and another wrote that reductions hurt innovation and quality. Additionally, a commenter suggested that the effect of the reductions will be to decrease dollars available for treating patients, and will indirectly limit access for patients with heavy care needs.

Response: We understand that some aspects of the payment environment have been uncertain at times. However, the total of 1997 payments is not comparable to the expenditures following the Balanced Budget Act (BBA) of 1997, which took effect in August of that year. The BBA led to a markedly lower use rate of home health services by 1999. Although the use rate has been rising since the historically low level brought by the BBA, the change in use rate is one reason for lower payments compared to the past. Analyses by the Medicare Payment Advisory Commission (MedPac) indicate that home health agency margins have been generally very healthy. Congressionally mandated updates and other payment changes under law have been made in the knowledge that agencies are generally not at risk of becoming insolvent. The continuing certification of new agencies and capital access for the industry, both of which are documented in MedPac's March 2009 annual report, are additional indications that Medicare payment is generally adequate or more than adequate. Furthermore, MedPac reported that freestanding agencies' cost per case grew at a relatively low annual average rate of 1.5 percent per year between 2002 and 2007. This low rate of cost growth compares favorably with annual payment updates of those years, notwithstanding Congressionally mandated reductions to some updates. Net updates for 2008 and 2009, incorporating the case-mix change adjustment, have been modestly positive. In terms of impacts on innovation, as we have noted elsewhere in our responses, some agencies have been able to make investments in new technology during these years. Home health quality measures have been generally stable or improving. In short, at this time, we do not believe that the survival of home health providers is threatened, and we have no indication that quality, access, and innovation are being compromised.

Comment: One commenter agreed with MedPAC's suggestion to establish ''profit/loss corridors'' as a financial safeguard for HHAs. Several commenters urged CMS to suspend further case-mix changes until a solution is found that ensures continuing access to home health care, and offered to work with CMS on the issues surrounding the case-mix change reductions. Several suggested that CMS meet with the industry to discuss the data and methodology, and find consensus. Another suggested that CMS refrain from additional case-mix adjustments until an impartial third party, the industry, and Congress review the process for analyzing case-mix.

Response: We appreciate the public's continuing effort to provide us with comments and creative suggestions. The Secretary does not have authority under current law to establish profit/loss corridors. Should these be mandated, we welcome suggestions about how to

implement them. Congress specifically addressed the possibility that nominal coding change might occur when it authorized (in BIPA legislation) the Secretary to offset such changes by reducing rates (see Section 1895(b)(3)(B)(iv) of the Act), and we are cognizant of the large reduction in costs per episode that accompanied prospective payment. Therefore, in 2007 we proposed and finalized a phased reduction in coding-based payment increases that we believe were not reflected by changes in underlying acuity, that were incurred between FY2000 and CY2005. We have continued to monitor nominal case-mix change through CY2007, and found continuing evidence that such changes were occurring. We received public comments on the case-mix change adjustment methodology in the past, and we have enhanced the model consistent with comments where necessary. As we noted in the proposed rule, after developing more data, we intend to test additional enhancements pursuant to comments we received in this rulemaking. At this time, we do not know whether any future results incorporating enhancements will measure additional real case-mix change than we have already accounted for using the existing model and data. We continue to welcome suggestions on how to improve our measurement method in a feasible and cost-efficient manner.

Comment: A number of commenters were opposed to the continuing decision to apply case-mix reductions to all agencies regardless of their average case-mix or rate of case-mix change. A commenter stated that the analysis focused on averages and does not account for States or regions with slower, more modest growth. A few commenters suggested that the Abt Associates reports showed that freestanding nonprofit agencies have not contributed to nominal case-mix change at a level comparable to for-profits, yet all agencies are suffering equal cuts. The commenter believes such a policy was unfair, and damaged agencies that CMS should be rewarding for their compliance, particularly non-profits. Several commenters stated that the reductions disproportionately affected hospital-based agencies or smaller agencies, particularly in rural areas.

While one commenter recognized the logistical problems if CMS were to excuse some agencies from further case-mix reductions, such as those that didn't have high average case-mix or which had not increased their average case-mix at a rate suggesting nominal change, the commenter wrote that CMS is obligated to apply policy fairly. The commenter suggested that we exempt agencies with low case-mix weights or which have not had excessive case-mix change from further across-the-board reductions.

Response: We continue to believe that it is more appropriate and feasible to implement a nationwide approach to case-mix change adjustment. An individual agency approach would be administratively burdensome and difficult to implement. Policies to address the identity of agencies in light of changes to organizational structures and configurations would need to be developed. Furthermore, smaller agencies might have difficulty in providing accurate measures of real case-mix change because of their small caseloads. We do not foresee being able to administer an individualized rate reduction fairly and effectively. Nor do we believe it would be possible to administer a regional or other classification-based reduction fairly. Any sort of special regional payment adjustments, the most common example being a rural add-on payment, would need to be legislated by Congress. Contrary to the statement a commenter made about the conclusions of the Abt Associates reports, the reports documented that freestanding voluntary/nonprofit agencies had relatively low average case-mix weights in FY2000. The analysis allowed changes in the ownership/affiliation composition of the population of agencies to contribute to real case-mix change, but it did not identify differences in case-mix growth since FY2000 within any class of agencies. Further, it seems unlikely that some significant number of agencies has avoided nominal case-mix change. It is counterintuitive to believe that agencies in general have not advanced and updated their application of OASIS and ICD9–CM diagnosis coding. In accordance with continuing educational efforts on the part of CMS, the State OASIS coordinators help agencies understand and apply OASIS, and other public and private assistance services that have developed around the proper and accurate interpretation of OASIS items and selection of the correct response to each item. That process of advancing and updating the application of OASIS is a natural outgrowth of the fundamental approach to payment adopted under the HH PPS.

Comment: A commenter wrote that CMS should adopt criteria to identify and protect ''safety net'' agencies from the impact of case-mix payment reductions, which admit patients based on need rather than on profitability. This commenter is concerned that these safety net agencies would be pushed out of the Medicare program by negative margins, creating a loss of critical patient access. This commenter stated that CMS should pay for the reasonable cost of care so that safety net agencies could be viable.

Response: Currently, the law does not provide for payment differentials for ''safety net'' agencies. Additionally, we believe that it would be extremely difficult to accurately identify safety-net providers, and any such process to identify and pay such providers differently could be inaccurate, prone to program vulnerabilities and costly to administer. Additionally, it would require CMS to enforce compliance with whatever criteria we used to identify such providers, to ensure that these providers continue to qualify for the payment differential. Rather, CMS is currently focusing on demonstrations which have a goal to reward providers based on the high quality of care provided, and savings associated with high quality, such as decreased hospitalizations.

Comment: Some commenters suggested further refinements to the case-mix adjustment model as a way of mitigating effects of the case mix change adjustment to the episode payment rate. The commenters mentioned giving credit for the absence of a caregiver, Medicaid status, residence in high crime areas, use of wound care and other supplies, use of innovative technologies, and for patients with advanced stages of debilitating chronic diseases.

Response: We appreciate the commenters' concerns and point out that we addressed the absence of caregivers in our CY 2008 final rule. OASIS item M0350 asks whether there are assisting persons in the home, other than the home care agency staff. On average, episodes without caregivers might be underpaid under the current case-mix model, but our analysis also showed that the payment difference was not large. Moreover, we continue to believe this variable raises significant policy concerns. We restate our belief that a case-mix adjustment should not discourage assistance from family members, nor should it make patients believe that there is some financial stake in how they report their familial supports while they are receiving home health services. Adoption of this measure of case-mix risks introduction of negative incentives into the case-mix adjustment system; these negative incentives potentially could have adverse effects on home health Medicare beneficiaries.

We also considered Medicaid status. After accounting for a broad range of clinical and functional factors which predict resource use, the presence of a Medicaid number was found to add a negligible amount to the predicted resource use, suggesting that having Medicaid is not a strong predictor of resource use. Given the administrative burdens of verifying the current Medicaid status of a patient, we judged that, on balance, adding Medicaid enrollment to the case-mix model was not warranted.

We know of no data to measure residence in high crime areas reliably for purposes of payment operations; nor are there studies documenting the role of this variable in patient-by-patient cost differences. The idea of incorporating technology use, such as wound care supplies and other innovative technologies, in determining the payment for specific patients raises significant policy issues about the role of the government in driving agency decisions about the mix of inputs to be used in delivering care. Our approach has been to document and pay in accordance with the average costs incurred when treating patients with different characteristics, but not to pay in accordance with agency technology choices. To the extent that costly technology is reflected in NRS costs and charges routinely available in administrative data, and use of such technology is the standard of care in specific circumstances, then we welcome proposals for identifying these situations in current data collection processes so that we can study their impact on NRS costs. We believe that any proposals from the public should balance the burden from adding complexity to coding systems and data collection processes on account of a small number of episodes against the impact on payment accuracy. Instruments such as OASIS are not designed to focus on uncommon situations. Regarding refinements for advanced stages of debilitating chronic diseases, we have concerns that measurement of this aspect of case mix would not be reliable, and could lead to inequities and nominal case mix change. Nonetheless, we welcome specific suggestions in future comment periods for measurement items and instruments that promise to reliably capture this dimension of health status.

Comment: Some commenters suggested that in the review of real vs. nominal case-mix change, CMS consider factors such as OASIS implementation, educational initiatives to teach agencies how to more comprehensively assess patient needs and more accurately code OASIS, improvements in documentation, and the quality of care.

Response: As we have noted in responding to similar comments in previous regulations, improved OASIS implementation, staff education, and improvements in documentation are indications of coding change, not an actual change in patient case-mix. While they may represent a much-desired improvement in the accuracy of data used to manage the care of patients, they do not represent cost increases related to the health status of patients. We have no basis to recognize the quality of care as a factor to consider in the review of nominal vs. real case-mix change. The legal basis for making payment reductions is nominal case-mix increases that can result from changes in coding practices and from coding improvements, as well as from financial incentives in the payment system.

Comment: Commenters cited an evolving home health population and changes in patient characteristics as factors to consider in the review of nominal vs. real case-mix change. A number of commenters mentioned that the patients entering home health are sicker, have more complex conditions with more co-morbidities, and require a more costly inter-disciplinary approach. One noted that the 1997 to 2000 increase of 13.4% in case-mix weights demonstrates the substantial effect that changes in patient characteristics can produce; this commenter wrote that if real case-mix could increase prior to HH PPS, it is unreasonable to assume that none of the change after that point is real.

Response: In our case-mix change model, we measured demographic and health status factors, and utilization indicators of health status, and then related them to the HH PPS case-mix weight in a regression equation. The methodology attempts to capture the effects of an evolving home health population by measuring the entire set of factors at two points in time. Having established the relationship between predictors and case-mix weight using data from the first time period, we then use the model to predict the case-mix weight based on the factors during the second time period. Therefore, this approach does consider changes in the home health population. To the extent that patients entering home health are sicker, have more complex conditions, and more comorbidities, the variables predicting the case-mix weight in the case-mix change model reflect such changes to a large extent. As we indicated in the proposed rule, we intend to test additional variables to pick up possible unmeasured population changes. It is not certain that these attempts will identify additional real case-mix change. If home health practice has evolved between FY2000 and today to provide an inter-disciplinary approach, this is not necessarily a change in the real case-mix of the treated population; it could well be a change in treatment practices, given that evidence from the case-mix change model and other evidence we have presented in previous regulations point to little change in the health characteristics of home health users. Notwithstanding the question of whether any shift towards an interdisciplinary approach has occurred, data cited by the Medicare Payment Advisory Commission and our own analyses of home health margins indicate that home health agencies are being adequately paid under the HH PPS.

Contrary to the assertion of the specific commenter that we had concluded that all of the change in case-mix was nominal, we identified nearly one-tenth of the difference between the average case-mix weight for FY2000 and CY2007 as real case-mix change. We allowed for that amount in the rate reductions. Regarding the large 13.4 percent change in average case-mix weight between 1997 and 2000 (that is, the last year of the IPS), in the 2007 proposed rule (72 FR 25393), we reviewed and discussed comparative OASIS data from the original Abt Associates case-mix study (1996–1998) and from FY 1999, as well as several studies of the effects of the Balanced Budget Act, and specifically, of the Interim Payment System (IPS).

The literature and data identified several changes in the health and demographic characteristics of the home health user population. An important implication of those studies and data was that patients with intensive or lengthy needs for nursing and personal care services as opposed to short-term or rehabilitative needs were less likely to be found in the national home care caseload as a result of the IPS (72 FR 25393). We also noted in that discussion that changes in therapy utilization during the final year of the IPS period, after the proposals for the HH PPS were issued, could have reflected an anticipatory response to the coming payment system. Such a behavioral response on the part of home health agencies would therefore have contributed to the 1997–2000 13.4 percent change in the average case-mix. As we indicated in our discussion, it is very possible that a certain amount of nominal change occurred during 1997–2000; this would have been due to the

period October 28, 1999, through September 30, 2000, which is the period after the proposed rule was issued.

Comment: Some commenters had specific criticisms of the real case-mix change model. Some wrote that the methodology for assessing changes in patient characteristics relies on DRG changes, but only half of HHA patients are discharged directly from a hospital to an agency. In commenting on the case-mix change model, some commenters stated that data on ownership structure were not related to patient characteristics. They went on to write that the methodology gave no consideration to changes in care delivery in other health sectors (for example, the growth in Medicare Advantage), or in reimbursement methodologies that drive patients into home health care.

Response: Far greater than half of the observation units—that is, episodes—in the samples had hospital discharge data. The model uses data from the last hospital stay the patient had before the home health episode. Approximately 90 percent of the random sample of episodes in the case-mix change model, regardless of the time period (FY2000 or CY2007), had a hospital stay record. Not all of these hospital stay records were classifiable to a specific DRG because of sample size considerations, but we were able to classify every hospital stay into a medical or a procedure group, based on information in the hospital stay record. For patients with multiple episodes, the last discharge did not necessarily lead directly to home health admission, but it would still reflect fairly recent health characteristics. For a small proportion of episodes, the hospital stay may have occurred distantly in time (but no more than four years earlier). In alternative models described in the Abt Associates Final Report (April, 2008), hospital stays for some conditions were not used if they did not occur relatively close in time to the home health episode, but the results did not change the essential conclusions we drew from the analysis.

The predictions of the case-mix weight from the model were adjusted for the ownership/affiliation category of the agency that delivered the care under the episode. We made this adjustment to account for the historically different coding practices and apparent case-mix levels associated with different kinds of ownership. We did this out of an abundance of caution, because of a paucity of literature explaining these differences. It is plausible that the large decline in hospital-based agencies that occurred after the last year of the IPS could have affected the national case-mix in a real sense. In any case, had we not made the ownership/affiliation adjustment, we would have found less real case-mix change from our analysis.

We disagree with the commenter's conclusion that we have ignored the effects of reimbursement methodologies that drive patients into home health care. Variables in the model account for prior utilization in acute care hospitals, long-term-care hospitals, inpatient rehabilitation facilities and skilled nursing facilities. The model relates these various kinds of utilization to the case-mix weight in the ensuing home health episode. We used the model and the levels of prior utilization that occurred by CY2007 to make predictions of the real case-mix weight for that year. In fact, the net effect of all the Medicare cost and utilization variables in the model was to raise the predicted average case-mix weight, consistent with what appears are the commenter's assumptions. However, the increase was small. To the extent that the nature of the relationship between the specific kind of prior utilization and the ensuing episode's case-mix weight has changed, the case-mix prediction methodology may not capture the entire impact of reimbursement changes in other parts of Medicare. However, in its Final Report (April, 2008), Abt Associates conducted a test for possible changes in the relationship between predictor variables and case-mix, and this test did not support the idea that changes in the model variables' relationship to case-mix had occurred. Moreover, we believe we have captured some of the other settings' reimbursement effects by measuring change in utilization of prior settings. In addition, the model includes an array of other demographic and health-related variables that are expected to detect change in the health status of the user population, which is the real underlying issue raised by reimbursement changes.

As we indicated in the proposed rule, we intend to test changes to the model that may represent the growth in Medicare Advantage.

Comment: Several commenters wrote that CMS' methodology for estimating nominal case-mix change is imprecise and relies on limited sources of data. One commenter noted that the methodology was not based on clinical analysis but on statistical inferences in a complex model that is so abstract and complex that significant data errors were undetected. The commenter noted that it is plausible that the average case-mix continues to grow, since the ratio of for-profit to nonprofit agencies increases each year, and for-profit agencies have higher case-mix. Several commenters wrote that nominal case-mix change estimate is a guesstimate, and is not sufficient or accurate. Some commenters suggested CMS engage additional consultants to use alternative methods of evaluation, and cross-compare outcomes, before the proposed 2011 adjustment is finalized. Another commenter asked for an independent audit of Abt's work.

Response: We believe that our methodology for quantifying the contribution of real case-mix change to total case-mix change between FY2000 and CY2007 is a reasonable approach, but it is only part of the evidence base for our conclusion that nominal case-mix change has been pervasive. As we noted in the proposed rule, the full evidence base was presented in a series of regulations, beginning with the May 4, 2007, proposed rule (72 FR 25393). We discussed a variety of statistical data, including but not limited to resource use measures in comparison to case-mix weight changes, shifts among severity levels of the clinical, functional, and service dimensions of the case-mix system, shifts in the share of high-therapy episodes, differential changes in responses among various OASIS items (payment-related items and non-payment-related items), and a detailed analysis of the evolution of OASIS guidance and manual instructions and definitions that could have affected case-mix item responses. We presented admission rates over time for five specific conditions suggested by commenters, and examined the time to admission for those conditions. These results were updated in the proposed rule, and suggested that changes were insufficient to explain the substantial upward trend in case-mix. We also noted the steep learning curve faced by agencies in adapting to the new environment presented by OASIS, resulting in improved coding. We also pointed out that coding changes are not foreign to any payer system when payment methodology becomes more dependent on provider ascertainment of health status information. The evidence base is the best available, given the infeasibility of auditing large chart samples from both time periods, which may be assumed to be the type of clinical analysis that a commenter suggests. As we noted in the proposed rule, we are investigating enhancements to the model to capture more elements of real case-mix change that may be unmeasured. However, whether these enhancements will reveal any additional real case-mix change than we have already measured is unclear at this time.

From the point of view of statistical methodology, the model is a basic linear model and not complex; although it includes several variables. Our application of the model relies on large, representative samples. The preparation of the data has been subject to some technical corrections, but the basic approach has remained the same and is not subject to significant error. Furthermore, insofar as there have been data errors, they have not been so significant as to alter by large amounts the size of the payment reductions we made based on the model findings. As we have noted elsewhere in our responses, the model does allow for the contribution of for-profit agencies to real case-mix change.

We have no plans for undertaking alternative methods of evaluation. An independent audit is not necessary because the model and results of the application of the model have been presented in detail in the Abt Associates reports. However, we do intend to test enhancements to the model (described in the proposed rule) and welcome suggestions from the public for modifications to the statistical approach and additions to the data that are cost-efficient to make.

Finally, as a point of clarification, the 2.71 percent reduction for CY 2011 is not a proposed adjustment. In the CY 2008 final rule (at 72 FR 49843) we promulgated our policy of a 2.75 percent reduction for 3 years (CY 2008, CY 2009, and CY 2010) and a 2.71 percent reduction for CY 2011. Nothing in this final rule changes what was finalized in the above rule, with regards to payment reductions to address the increase in nominal case-mix.

Comment: Some commenters believed that the increased therapy needs or increased involvement of physical therapists in assessing patients have contributed to appropriate growth in HHRGs. They wrote that the change in focus from disease management to restorative therapy has increased HHRGs and benefited patients. A few suggested that the process for evaluating case-mix change related to therapy utilization must include in-depth review of the merits of individual claims, as the limited use of proxies is unreliable. Several commenters believed that the analysis failed to adequately evaluate whether changes in case-mix are due to abusive over-utilization of therapy, fraudulent or abusive coding, erroneous coding, revised coding instructions, or improved quality coding. Where changes are due to abusive or fraudulent practices, several commenters suggested that CMS address those abuses with the specific providers, rather than applying a punitive adjustment to all agencies. Alternatively, commenters suggested CMS use enforcement to conduct targeted claims review and deny payment where case-mix weights are not supported by the plan of care.

Response: We agree that there has been a shift toward rehabilitative services, but we believe commenters are confusing a change in the home health ''product'' with actual change in the health status of the treated population. As MedPAC has noted for years, with the implementation of the HH PPS, the service payment unit underwent changes: the unit of payment changed from visits to 60-day episodes, and the content of the home health product changed from that of the 1997–2000 period—consisting of fewer visits, shorter stays, and more therapy with less aide care (MedPAC, March 2004, ''Report to Congress: Medicare Payment Policy'', Section 3D, ''Home Health Services''). In any future enhancement of the real case-mix change model, we may investigate allowing for the possible increased use of physical therapists as the assessing clinician. We would do this on the assumption that increased use of therapists to make assessments is a change that is not a consequence of the agencies' learning curve in the HH PPS environment or of new financial incentives that began in October 2000. We would do this despite the fact that it could be stated that differing assessment results arising from the use of nurses vs. therapists as assessing clinicians do not signify differences in the health status of the treated patient. In any case, we expect that such a change to the model would have a very small impact on our conclusions.

To the extent that abusive over-utilization of therapy and fraudulent or abusive coding are responsible for case-mix growth between FY2000 and CY2007, it would be preferable to remove agencies engaging in these activities from the data analysis. However, it is difficult for us to identify these agencies on a large scale, so we find the commenter's suggestion impractical. Furthermore, we believe that the overwhelming majority of providers are not committing fraud, which would mean that eliminating the fraudulent providers would not have a large impact on our results. If commenters know of fraud being committed in their areas, we urge them to inform the Office of the Inspector General and the CMS Regional Office. As stated earlier, CMS is committed to addressing suspect fraudulent activities, especially those in areas where we see suspicious outlier payments, and will monitor and aggressively pursue actions towards agencies where inappropriate billing of outlier payments is identified.

Comment: Several commenters suggested we conduct an impact analysis of the proposed rule relative to case-mix, include an evaluation of access in each year of any adjustment, and consider all factors related to access. These commenters felt that the impacts in the proposed rule were factually and legally inadequate and therefore violated the Regulatory Flexibility Act.

Response: We appreciate the commenter's suggestion; however, our current approach to impact analysis does include the effect of the rate reduction related to nominal case-mix change. Our impact analysis is subject to OMB review and meets legal requirements. We will consider how to increase our monitoring of access going forward. We would appreciate any specific suggestions from commenters on ways to do this.

Comment: A few commenters questioned the assumptions surrounding LUPA episodes which were used in the case-mix change analysis. One wrote that nearly all ''creep'' may have been offset if CMS had modified its actuarial assumption of 5 percent LUPA incidence to actual occurrence once PPS was in place. The commenter asked that we disclose the LUPA incidence for 2001 through 2006. The commenter felt that using a 5 percent LUPA incidence, rather than the higher, actual LUPA incidence, has led to agencies being underpaid. This commenter added that instead of lowering rates using a ''creep'' theory of justification, CMS should have raised the base rate calculation methodology with the refinement process, at a minimum for the LUPA mis-application and also for the real need severity CMS determined exists. This commenter wrote that the combination of LUPA incidence, an outlier rate below 5 percent, changing the single therapy threshold to multiple therapy thresholds, and the increased incidence of high therapy cases constitutes more than 100 percent of the observed increased in the average case-mix weight.

Response: Based on a 10 percent random beneficiary sample, our data show the LUPA incidence rates from 2001 to 2007 were the following: 15.06 percent, 14.11 percent, 13.35 percent, 12.53 percent, 12.12 percent, 11.16 percent, 10.54 percent. We note that LUPA incidence rates, while higher than the forecasted 5 percent, continue to decline. LUPA episodes were not used in the measurement of case-mix

change in either our analysis or in the Abt Associates model of real case-mix change. We have no evidence that LUPA episode assumptions caused agencies to be underpaid; in fact, margin analysis shows PPS payments have been adequate. It should be recognized that we proposed to adjust the episode national standardized payment amount to be consistent with an outlier expenditure proportion of less than 5 percent of total outlays. This upward adjustment is a continuation of the methodology we have used since the beginning of PPS; the upward adjustment is simply to provide for a lower rate of outlier expenditures than the 5 percent assumption we have traditionally used. We made this proposal in conjunction with the proposal to cap outlier payments at 10 percent on an per-agency basis. We have no basis to change payment rates on account of the refinement of the therapy thresholds. Even if agencies return to more clinically based therapy treatment plans, resulting in a new distribution of therapy visits per episode and reduced total expenditures, we would not make any payment rate changes in isolation from other issues, such as the change in the mix of visits since the original PPS final rule, and change in the total number of visits in a 60-day episode. Similarly, we do not believe it is appropriate to adjust payment rates for the deviation of LUPA episodes from the forecasted 5 percent, in isolation from other issues, such as addressing the issue of lower visits per episode existing today, as compared to the number of visits per episode on which the HH PPS rates were originally based. We believe that the appropriate time and place to deal with any re-estimates, in these multiple areas, is if and when a rebasing for the rates were to take place.

Comment: A commenter wrote that the elimination of the single therapy threshold was an attempt by CMS to align payment incentives with patient care needs. This commenter felt the case-mix change primarily reflects growth in therapy utilization. A different commenter asked CMS to clarify how going from single to multiple therapy levels did not constitute a ''double dip'' penalty. This commenter wrote that the multi-level therapy equation model HHRG modifications may have lowered the relative value for all higher therapy cases, but the commenter couldn't confirm this since CMS did not release the data. The commenter stated that ''re-jiggering'' of service factors was likely directed toward lowering reimbursement rates and having therapy services delivered in a more clinically driven manner. The commenter added that the relative loss of aggregate case-mix weight under the 4–Equation model equals measured case-mix weight change, which is tantamount to a ''double dip''. Another commenter wrote that the data he analyzed showed that 95 percent of case-mix growth was a direct result of higher levels of service domain in care delivery under PPS. He added that when PPS was originally proposed, and again in 2007, CMS acknowledged that it did not have good data to measure or apply case-mix based on patients' service needs, yet CMS stated that it believed that the multi-level therapy thresholds was an improvement over the single threshold approach.

Response: The following table illustrates the change in the distribution of therapy visits per episode since FY2000:

PERCENT OF TOTAL EPISODES BY NUMBER OF THERAPY VISITS PER 60-DAY EPISODE: INTERIM PAYMENT SYSTEM AND HH PPS

Number of therapy visits	Time period							
	FY2000	2001	2002	2003	2004	2005	2006	2007
None	60.0	54.5	52.3	51.2	49.9	49.6	49.6	49.8
1 to 3	9.7	9.1	9.4	9.6	9.7	9.6	9.3	9.1
4 to 6	7.4	8.0	8.3	8.3	8.4	8.3	8.1	7.9
7 to 9	6.2	6.4	6.4	6.2	6.1	6.1	5.9	6.0
10 to 12	4.8	8.3	9.2	10.4	11.3	11.8	12.3	12.6
13 to 15	3.4	4.8	5.3	5.6	5.9	6.0	6.2	6.3
16 to 18	2.5	3.3	3.5	3.5	3.7	3.8	3.8	3.8
19 to 20	1.2	1.4	1.5	1.4	1.4	1.4	1.3	1.3
21+	4.7	4.2	4.1	3.8	3.7	3.5	3.5	3.2
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Notes: FY2000 data from 100% sample of claims from Oct. 1, 1999, through Sept. 30, 2000.
Data presented for 2001 through 2007 are Calendar Year data.
Claims were grouped into 60-day episodes.
PPS data based on a 10% random beneficiary sample of PPS episode claims beginning with 1/1/2001.

We agree that growth in therapy utilization of ten visits or more was a significant factor in case-mix change, because the ten-visit therapy threshold produced a large increase in an episode's case-mix weight. The table above shows that episodes of ten to eighteen therapy visits grew steadily as a proportion of total episodes under HH PPS. Ten to twelve therapy visits, a range that would generally be most profitable to agencies, grew the most, and by 2007 such episodes accounted for about one quarter of all the episodes that had a therapy visit. These episodes, of course, also were among those with the highest case-mix weights and had a minimum case-mix weight of 1.4847.

One goal of the case-mix refinements was to better match payments with agency cost experience under PPS; thus we used 2005 data for estimating the final case-mix model that was used for the 153-group system. Changing to multiple therapy thresholds with a gradual increase in payment better aligns costs and payments and avoids incentives for providers to distort patterns of good care that would occur at each proposed therapy threshold. As a disincentive for agencies to provide more care than is appropriate, we proposed that any per-visit increase incorporate a declining, rather than constant, amount per added therapy visit. It should be understood that the refined case-mix methodology redistributed the resource costs expended in 2005 to the new set of 153 groups we defined from the severity levels developed from the four-equation model generating OASIS item scores.

Instead of a single high therapy range, one based on average resource costs for all episodes with 10 or more therapy visits (including those with the very highest number of therapy visits), the refined system had multiple therapy ranges, with the payment addition for therapy being based on all episodes with therapy visits in the stated range. Therefore, the right tail of the distribution (that is, cases with the highest therapy visits and thus the highest resource costs for therapy) is not figuring into the payment increment until the 20+ therapy visit level is reached. Thus, it was our intention to have lower payments for episodes with 10 to 12 therapy visits, so as to better align costs and payments.

The redistribution of resource costs among the new 153 groups resulted in some lowering of case-mix weights, as just described, but all the resource costs expended in 2005 were accounted for in the payment system. The final case-mix change adjustment addresses nominal case-mix change and is applied across all case-mix groups in a similar manner. Therefore, the final case-mix adjustment is completely separate from the realignment of payments to the 153 groups, and thus there was no double-dipping. In sum, the multiple therapy thresholds and the case-mix change adjustment are unrelated and do not doubly adjust the rate as each adjustment is clearly warranted by the data.

We do not have enough information to verify the commenter's finding that 95 percent of case-mix growth was a direct result of higher levels of service domain in care delivery under PPS.

Comment: Several commenters wrote with suggestions or alternatives to the case-mix analysis. One commenter wrote that CMS should continue to work on developing post-acute care national assessment tool for use across all settings, which would allow CMS to better determine what settings were appropriate for patients based on acuity. It would also allow CMS to understand how changes in home health case-mix are affected by the type of patient admitted to home health. Some wrote that CMS should allow implementation of OASIS–C before any further case-mix reductions are made. A commenter suggested that we fully analyze and compare information within OASIS–C with the development and testing of the Continuity Assessment Record and Evaluation (CARE) instrument. Another commenter felt that the data from OASIS–C would be helpful to CMS in determining real changes in case-mix rather than those stemming from coding or documentation improvements.

A number of commenters felt that the proposed 2011 adjustment was too steep, particularly given low or negative profit margins, and recommended a minimum 4-year phase-in; another suggestions that we consider the impact on low-margin agencies before finalizing the rule. Some commenters suggested that the complexities of the case-mix methodology warranted making relevant CMS staff and contractors available to respond to questions regarding the assessment methods prior to expiration of the comment period. Additionally, these commenters suggested that CMS make all data used in the analyses available, and provide a 120-day comment period to allow time for expert analysis to evaluate the methodology and findings. A different commenter was strongly opposed to reductions for 2011 until more analysis of medical necessity of the care provided was complete. This commenter encouraged us to reduce or eliminate the creep attributed to the shift to provision of higher therapy services unless clear evidence existed that the therapy services were not medically necessary. This commenter suggested we make a distinction in the application of creep between therapy and non-therapy HHRGs, and recommended that physical and occupational therapists be added to MAC review departments with mandatory education and experience as qualifications for medical review.

Response: We thank the commenters for these thoughtful comments and suggestions. We assure the commenter that we are continuing our work associated with the post-acute care demonstration. We are currently in the early stages of data analysis of the assessment data and resource data which has been collected to date. We will finish data collection by the end of calendar year 2009. We remind the commenter that the analysis of these data is a multi-year project, and that the analysis will consider the data collected via the CARE instrument, the validity and reliability of those data, and the strength of the items as payment predictors. CMS plans to present the analysis of the data collected during the demonstration and associated recommendations to Congress in the summer of 2011. Regarding the commenters' suggestions that we wait to make further case-mix reductions until we assess the OASIS–C data, we remind the commenter that the OASIS–C revisions did not significantly change payment items. We believe that the commenter may be suggesting that CMS analyze OASIC–C non-payment items to assess whether these new items would enable CMS to better identify the health status of the patient, and whether these new items might be more reliable in assessing real patient acuity change versus that which is unrelated to real changes in acuity (nominal). It is important to note that because we are just beginning to collect these items in CY 2011, that sort of comparative analysis would only be possible after several years of OASIS–C data collection. We may consider the suggestion that we account for increases in nominal case-mix over a longer period of time, in future rulemaking. In this final rule, we are not accounting for additional changes in nominal case-mix which we identified from current data analysis. Rather, we are maintaining the policy, finalized in CY 2008, to reduce CY 2010 base episode payments by 2.75 percent. With regards to the suggestion for a 120-day comment period, we are unfortunately unable to adopt such a comment period given our rulemaking timeframes, but we will continue to make every attempt possible to share our analyses with the public in as timely as possible. Regarding the commenter's suggestion that CMS should assess the medical necessity of therapy visits before applying up-coding reductions, as we described in an earlier comment, we find this suggestion impracticable. With finite resources, it would be challenging to perform a medical review on every claim which includes therapy.

Again, as a point of clarification, the 2.71 percent reduction for CY 2011 is not a proposed adjustment. That percentage reduction was promulgated in the CY 2008 final rule (72 FR 49843).

Comment: A commenter stated that while he did not assess changes in home health case-mix, an increase in case-mix unrelated to severity in 2007 confirms the need for continuing review of annual case-mix change. The commenter noted that nominal changes in case-mix had been found when major revisions were implemented in other payment systems, suggesting particular scrutiny of the 2008 changes in case-mix was warranted. The commenter wrote that if additional nominal case-mix change was indicated, CMS should adjust payments as appropriate. The commenter further recommended that we combine the planned reductions for 2010 and 2011, and reduce payments in 2010 by 5.5 percent, and that payments should be rebased to a level equal to average costs in 2011.

Response: We thank the writer for these comments. We agree with the commenter that we need to continue to analyze current data as they become available to us and update our

identification of nominal case-mix using these more current data. We are currently analyzing 2008 data to assess the impact of our CY 2008 refinements, and determine the effect these refinements may have had on nominal case-mix growth and will address the need for additional reductions to the HH PPS rates in future rulemaking.

Comment: Another commenter wrote that CMS uses MedPAC's reports of strong profit margins and high levels of new entrants to bolster the view that access will be unaffected after the full creep cutbacks are implemented. This commenter wrote that an industry association disagrees with MedPAC's methodology, and concluded that one-third to one-half of HHAs would lose money when creep reductions are fully implemented. The commenter questioned MedPAC's use of a sample of HHA cost reports representing less than 60 percent of HHA visits. This commenter asked that the full information from MedPAC be released and subject to review since CMS is supporting its case-mix reduction using that report.

Response: We would like to assure the commenter that the analysis and associated methodology CMS used to differentiate between real and nominal case-mix growth involved extensive analysis, which is fully documented in the Abt report, publicly available via the HH PPS Web site at *http://www.cms.hhs.gov/Reports/downloads/Coleman_final_April_2008.pdf.*

We understand that the commenters are concerned about whether we are taking into consideration the financial conditions of hospital-based home health agencies. As MedPAC noted in its March 2009 report, financial margin estimates using hospital-based providers are impacted by the allocation of overhead costs from the hospital. We agree with this assessment and believe that using this information would not provide an accurate view of the overall industry margin or the impact of the proposed change to the payment system.

Comment: A commenter disagreed with our choice of data used for the creep analysis, saying that he was not convinced that data from the final year of IPS could serve as a base period from which to measure nominal growth in case-mix. The commenter questioned whether these data were representative of post-PPS, and noted that there was a learning curve with OASIS. The commenter wrote that until we made the ''derived base period'' information available to the public, we should defer further creep adjustments and roll back the first two stages. He also questioned Abt's use of just 313,447 IPS OASIS assessments, and was concerned that 18 percent of the episodes could not be evaluated since the OASIS could not be reliably linked to claims. He also noted that much has been made of improvements in OASIS coding over time, which suggests that the OASIS was not properly coded at the time of IPS. He questions the validity of this sample since many HHAs were not filing OASIS at the time, and concluded that it was illogical to assume the IPS data could be reliable bases for measuring creep. He also suggested we make public the data showing actual use of S2 and S3, and the IPS data used as a proxy for S2 and S3 cases. He noted that there was no M0825 data in OASIS for the final IPS period; therefore one could argue that the final IPS data understates case-mix.

Response: We disagree that OASIS data collected during the last year of IPS were so poor as to be unusable to measure the case mix during that period. Agencies were not supposed to be unfamiliar with OASIS in the fall of 1999. Medicare first proposed making OASIS mandatory in March 1997. The development of OASIS had been supported and publicized by a large industry group over the years (transcript of June 24, 1997, meeting of National Committee on Vital and Health Statistics, accessed at *http://www.ncvhs.hhs.gov/970624b1.htm#oasis*). OASIS was discussed in professional and research journals (for example, see *Home Healthcare Nurse,* May 1997, Vol. 15/5: 340–342). OASIS version B–1 was released in October 1998, one year before our observation period for the IPS baseline began. After first publishing a final regulation in January 1999 whose effective date was delayed on April 27, 1999, Medicare re-finalized the OASIS regulations in June 1999. Agencies were instructed to begin OASIS data collection for Medicare, Medicaid, and all other skilled services patients by July 19, 1999. This was 2.5 months before the beginning of our IPS baseline observation period, though they did not have to transmit data (other than for testing purposes) until August 25, 1999. The Health Care Financing Administration (HCFA), CMS's predecessor agency, issued a comprehensive OASIS Implementation manual in July 1999 containing item-by-item instructions about how to complete the OASIS assessment. It was for the use of HHA agency staff who would be implementing OASIS as a uniform core data set. HCFA conducted a national meeting of State OASIS coordinators in mid-September 1999 to train them in responding to agency requests for information. Four million assessments were submitted by HHAs to State agencies from July 1999 to January 2000 (CMS–3006–F, Dec. 23, 2005). This is an indication that agencies were actively working with OASIS from the start of the OASIS effective date. Our inability to match all simulated episodes to an OASIS stems mainly from the fact that time points of data collection for OASIS before HH PPS did not necessarily match the starting points of simulated episodes. During that period, OASIS was collected for outcomes purposes, not payment purposes.

The learning curve with OASIS is an important reason why nominal case-mix growth should be expected. However, we based our case-mix change adjustment on the evidence that patient health status did not change substantially, notwithstanding that improved understanding of and application of OASIS occurred. Contrary to the commenter's implication that the IPS sample was small, our sample size of hundreds of thousands is extremely large. Scientifically, sample size adequacy does not hinge on the ratio of the sample to the total population, but does depend on the actual absolute numbers of observations. Regarding the 18 percent of IPS episodes without a matched OASIS, we appreciate the commenter's concern, but we have good reason to believe that the sample we used is representative. Based on our understanding of the main cause of the OASIS shortfall (described above), we do not have reason to infer a bias in the assessments that we do have. We also note that the sample's average is consistent with an average from an initial episode sample. Initial episodes are more likely to have a matched OASIS (89 percent for initial episodes vs. 75 percent for subsequent episodes) so using data based on initial episodes should reduce concerns about sample representativeness. The estimate of average case-mix weight that we get from the sample combining initial and subsequent episodes differs from the estimate we get from the initial episodes sample in the direction we expect (1.096 vs. 1.125). That is, the estimate from total (initial and subsequent) episodes is lower because health conditions measured in OASIS and used in the case-mix system tend to be more severe around the time of admission. Furthermore—and most important in terms of the basis for our policy decision to adjust payment to compensate for nominal case-mix change—using an initial episode sample would produce the same percentage

growth in case-mix as using a combined initial and subsequent episode sample. As we stated in the CY 2008 final rule (72 FR 49833): ''We used all episodes rather than just initial episodes. This change in our sample selection approach does not materially change the estimate of case-mix change, whether comparing the baseline to HH PPS 2003 or HH PPS 2005.'' Finally, modeling case-mix on an IPS sample that could possibly deviate in some respects from a fully representative sample would not necessarily produce distortions in the relationships found by the modeling procedure. Our conclusions about real case-mix change depend upon those relationships.

As we have noted elsewhere in our responses to comments, we believe we have made available highly detailed information about our data and methodology in the Abt Associates reports (April 2008 and August 2009) and in our regulations. For years, claims and OASIS data have been routinely available for purchase from CMS for researchers who wish to analyze it and can guarantee the security of the data. We published data on the rates of use of S2 and S3 under the IPS baseline period and 2003 in Tables 8 and 9 in the May 4, 2007 proposed rule (72 FR 25396–25399). The table in this section, in a response to a comment, provides detailed annual therapy visit distributions and thereby reflects S2 and S3 rates year by year. We did not use M0825 in determining S2 and S3; instead, we used the therapy visits reported by providers on the matched paid claims.

Comment: A commenter asked that we re-examine the case-mix weights for congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and similar chronic conditions. She wrote that we claim HHAs are seeing fewer of such patients, and that she believes this is either due to coding practices or to agencies not accepting these patients. The commenter believes that the current method for accounting for patients with these conditions results in a very low case-mix weight. This low case-mix weight, coupled with high nursing needs, causes these patients to exceed available reimbursement, leading to a loss for the agency. The commenter asked that we increase points for these diagnoses, refine how shortness of breath is assessed and points calculated, and consider the speed at which such patients can perform Activities of Daily Living (ADLs), and not just whether the patient can do the ADL independently.

Response: The case-mix model we finalized in the CY 2008 final rule recognizes more diagnoses than the original (FY2000) HH PPS model, and it includes the specific diagnoses mentioned by the commenter, CHF and COPD. Also, the CY 2008 case-mix model recognizes resource-intensive interactions (that is, combinations of conditions within the same episode). The model specifically recognizes the interaction of pulmonary conditions and ambulation: the cost of serving pulmonary patients with a limitation in ambulation is more during an initial episode, and this combination increases the case-mix score. We believe this interaction case-mix item does capture the burden of COPD on ADLs. Shortness of breath, as measured by OASIS item M0490, provides additional points for initial episodes. Providers receive points for these and other conditions identified from statistical modeling of the relationship between diagnoses and OASIS measures on the one hand, and resource costs on the other. Agencies also receive points for secondary diagnoses, thereby accounting for multiple co-morbidities.

Furthermore, we implemented a case-mix adjusted payment for non-routine supplies, such as those related to ulcers or wounds. All of the point values in the case-mix model represent the average addition to the resource cost of the 60-day episode when a patient has the condition associated with the points. The fact that agencies may encounter some cases more costly than the case-mix-adjusted payment is a result of the variability in patient needs inherent in the population. We believe that, on average, this model aligns payment and agency costs with acceptable accuracy. As shown in Table 1 of the CY 2010 proposed rule (74 FR 40958), the proportion of episodes (initial episodes and all subsequent episodes) where the patient was discharged from the hospital prior to entering home health and had a hospital principal diagnosis of CHF has decreased by more than one-third since FY 2000. We did not publish a similar statistic for COPD. The statistics in Table 1 do not reflect coding practices in home health agencies; the conditions in Table 1 come from the hospital principal diagnosis preceding the episode (where the discharge occurred within the 14 days before the first day of the episode). As for refining the dyspnea and ADL measures in OASIS, we have reviewed all items in the course of developing OASIS–C. We made changes to selected items where a need for improvement was apparent. This review did not result in significant changes along the lines suggested by the commenter. Furthermore, it is unclear how the speed of ADL performance affects the resource costs for nursing care, beyond the added costs already accounted for in the point-bearing items mentioned earlier in this response. Finally, all changes to the OASIS instrument have to be balanced against the added burden imposed on the agency to measure performance reliably and accurately.

To summarize, we are moving forward with our existing policy, as implemented in the August 22, 2007 CY 2008 final rule with comment, of imposing a 2.75 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor for CY 2010. We will continue to monitor any future changes in case-mix as more current data become available. We will also continue to look at ways to enhance the Abt model, and depending on the availability of newer and additional data, look to take into account factors that might yet be unmeasured in the current model. Given the continued growth in nominal case-mix, we expect to revise upward the 2.71 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor for CY 2011 in next year's rule. Analysis in next year's rule will update the measure of the nominal increase in case-mix and compute the appropriate percent reduction to the national standardized 60-day episode rates and the NRS conversion factor to account for that increase.

C. Proposed CY 2010 Rate Update

1. The Home Health Market Basket Update

We proposed a HH market basket update of 2.2 percent for CY 2010. This update was based on IHS Global Insight Inc.'s first quarter 2009 forecast, utilizing historical data through the fourth quarter 2008. Since publication of the proposed rule, we have a revised market basket update based on IHS Global Insight Inc.'s third quarter 2009 forecast, utilizing historical data through the second quarter of 2009. The final HH market basket update for CY 2010 is 2.0 percent. A detailed description of how we derive the HHA market basket is available in the CY 2008 Home Health PPS proposed rule (72 FR 25356, 25435).

Comment: One commenter stated the market basket increase of 2.2 percent would not be sufficient to cover the increased costs of implementing OASIS–C, CAHPS, as well as increases in staffing costs. The ongoing phase-in of the case-mix ''creep'' adjustment would add to the financial burden of receiving a market basket increase

which is lower than the previous year's 2.9 percent. According to MedPAC, 25 percent of HHAs have negative profit margins. The increase in costs of operation will have a negative impact on the financial viability of these agencies.

The commenter noted that not-for-profit HHAs are investing more of their revenue in attracting and retaining qualified HH staff. The shortages of nursing and physical therapy personnel are a major challenge. HHAs compete with other providers to attract these professionals.

Response: We disagree with the commenter that the 2010 market basket update is not sufficient. The home health (HH) market basket is not designed to account for changes in total costs (such as those associated with the implementation of OASIS–C or other initiatives), but rather it is intended to measure the input price pressures that the average home health provider is expected to face in the coming year. The composition of the market basket itself is made up of a set of mutually exclusive and exhaustive cost categories that reflect the cost structure of the industry (in a given base year). The HH index's cost shares (or weights) are based on data reported on the Medicare cost report forms and are specific to home health agencies. Each cost category is assigned an appropriate price proxy whose projected movements are weighted by their respective cost shares resulting in the actual market basket update.

We recognize that HH providers compete with the rest of the health care industry for nurses, physical therapists, and other health care personnel. To the extent that the cost structure of the HH industry changes over time, such as a greater share of expenses being devoted to wages and salaries, for example, that change in share is picked up during the rebasing process of a market basket. It has been our experience that the cost structure of the HH industry does not vary substantively from year to year. As a matter of practice, however, CMS periodically rebases its market baskets to reflect updated cost structures. The current HH market basket is based on Medicare cost report data from 2003 and, we believe, reflects the appropriate cost composition of the industry. We will continue to closely monitor the cost structure of the HH industry and will propose to rebase the market basket, as appropriate. Notably, the final update contained in this rule does reflect the expected competitive wage pressures associated with hiring health care personnel in the coming year.

Comment: One commenter stated support for our proposal to provide the full market basket update of 2.2 percent in CY 2010. The commenter stated that this measure provides relief to HHAs that have been subject to market basket cuts for several years including a 0.8 percent reduction in the market basket for 2004 (July to December) and 2005, and a full 3.6 percent market basket reduction in 2006 (per provisions of section 5201 of the DRA of 2005).

Response: We appreciate the commenter's support. We will incorporate the final market basket update of 2.0 percent into the CY 2010 HH PPS rates.

2. Home Health Care Quality Improvement

As part of the CY 2010 proposed rule, we proposed to consider OASIS assessments submitted by HHAs to CMS in compliance with HHA conditions of participation for episodes beginning on or after July 1, 2008 and before July 1, 2009 as fulfilling the quality reporting requirement for CY 2010. We proposed to reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements in CY 2010 and each year thereafter on an annual cycle July 1 through June 30 as described above. HHAs that meet the 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.

In the proposed rule we described the impending transition from OASIS–B1 to OASIS–C. This revision to the current OASIS version B–1 has undergone additional testing, and has been distributed for public comment and other technical expert recommendations over the past few years. CMS received OMB approval to modify the OASIS data set and will require that this new version of OASIS (OMB # 0938–0760) be collected on episodes of care beginning on or after January 1, 2010.

In the proposed rule we also noted that as a result of implementing OASIS–C, we will update Home Health Compare to reflect the addition of the following 13 new process of care measures:

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

Also under consideration are three additional process of care measures that may be added to home Health Compare based on results of consumer testing. Those additional process measures are:

- Drug education on high risk medications provided to patient/caregiver at start of episode,
- Potential medication issues identified and timely physician contact at start of episode,
- Potential medication issues identified and timely physician contact during episode.

Comment: One commenter stated that he believes a six to twelve-month delay in implementation of OASIS–C would be necessary to accommodate a reasonable phase-in of such a significant change in OASIS. The commenter stated that the vendor community reports that it is not yet ready for OASIS–C. As a result, agencies can neither test the software changes needed nor can they begin training their clinical and information systems staff on the changes. As of mid-September 2009, CMS had not released the final interpretive guidelines for OASIS–C. There is simply not enough time to do all the planning, testing and training needed to successfully implement OASIS–C on January 1. The commenter believed outcome measurement is far too important to be implemented without adequate training and testing, and wrote that changes in OASIS implementation of this magnitude deserve a proper implementation process. He felt that the home health community has waited for many years for some of these changes, so waiting a few more months to do it right would be prudent.

Another commenter stated that our proposal to require home health agencies to transition patient assessment data collection from OASIS B1 to OASIS–C on January 1, 2010 was considered to be an appropriate timeline when proposed. However, he felt that in

light of the recently issued version OASIS–C (August 2009) and the fact that guidance and Q&As have not yet been made available, this would no longer be an appropriate target timeline. The commenter wrote that this timeline would not give software vendors and home health agencies sufficient time to complete programming, testing and education of clinicians. The commenter appreciated that CMS is undertaking several venues for educating providers on OASIS–C to ensure that all home health agencies have access to free training, but stated that there are too many unresolved issues to meet a January 1, 2010 implementation date. The commenter requested that CMS delay implementation of OASIS–C implementation until April 1, 2010.

Response: We appreciate the magnitude of the effort required to transition to OASIS–C, but we believe that it will offer substantial benefits, in terms of improved support for agency quality improvement efforts and provision of enhanced quality information for providers and beneficiaries. The new data set also incorporates process of care items that measure agencies' use of evidence-based practices that have been shown to prevent exacerbation of serious conditions, can improve care received by individual patients, and can provide guidance to agencies on how to improve care and avoid adverse events. Making these improvements is a high priority for CMS, which is why we have proceeded on a well-considered course of data set development and field testing, solicitation of public comment, and revision of the data set, on a deliberate schedule over the past 4 years. Our experience in field testing showed that agency staff could be trained on the new and modified items in a relatively short period of time, and welcomed the improvements to the data set. We released the post-testing version of the data set in March 2009, and the initial OASIS Data Specifications on July 1, 2009, so that vendors could begin to develop the needed system changes. CMS has not received feedback from the vendor community to date, relating to lack of readiness for OASIS–C. We believe that software vendors who took timely advantage of the resources made available will be prepared for the OASIS–C transition. In addition, the State systems are being configured to accept OASIS–C as of January 1, 2010, as is the updated home health PPS grouper software. While such a major change will never be easy, we believe that the benefits to be realized and the burdens of delaying the process at this point, and argue for proceeding with this transition as scheduled. The immediate need of HHAs related to the OASIS–C instrument is to understand what the new, changed and deleted items are. This information has been available since August. Agencies will not be introduced to new quality measures until September 2010 and additional resources related to these will be made available. We will shortly be posting the final OASIS–C User Guidance Manual, and we will be offering free training teleconferences through the Medicare Learning Network. We urge all providers or vendors who have questions about OASIS–C or the transition to take advantage of all of the resources that CMS has provided, which can be accessed through the CMS Web site, the Quality Improvement Evaluation System (QIES) Technical Support Office (QTSO) Web site, and our State OASIS Education Coordinators.

Comment: One commenter stated that it is his understanding that the current number of quality measures available through Outcome-Based Quality Improvement (OBQI) is 41, rather than 54, with plans by CMS to expand to 54 once process measure data are available from OASIS–C data collection. The commenter recognized the value of adding process measures to Home Health Compare as additional consideration by the public in search for home health services. However, the commenter believed that 13 process measures, in addition to the 12 quality measures already publicly reported, will only serve to overwhelm beneficiaries. He wrote that the important considerations related to processes are assessment of need and implementation of interventions.

The commenter recommended that measures related to ''plan of care'' not be publicly reported since this is information not essential to the agency selection process. He added that current regulations require that all services, regardless of professional practice requirements, be included in the plan of care.

Response: We agree that assessment of need and implementation of interventions are important considerations related to processes, but we also believe that proactive planning for appropriate interventions is an indicator of quality care. HHA clinicians play a key role in the formulation of the plan of care and when interventions such as diabetic foot care or falls prevention are stated clearly in the plan of care, they are available for reference by all staff who provide care for the patient, thereby ensuring that efforts are coordinated effectively. The seven process measures related to the plan of care are National Quality Forum (NQF) endorsed measures of accountability for HHAs. They assess adherence to recommendations for best clinical practice which we believe is an essential piece of the agency selection process.

Comment: One commenter suggested that CMS use caution when selecting indicators which may focus solely on processes that may not have been tested to be predictors of quality.

Response: The new process measures are NQF-endorsed, in addition to extensive testing and evaluation of CMS based on criteria that include, but are not limited to: Addressing a national health goal or priority area, consistency with clinical practice guidelines and action-ability of the measures (that is, the measures' susceptibility to experiencing improved outcomes through intervention). CMS will continue to provide meaningful, relevant, timely, and consensus-based measures.

Comment: CMS received several comments supporting the value of adding the new process measures.

Response: We appreciate the industry's willingness and encouragement regarding adopting these new methods of reflecting the quality of care provided to Medicare beneficiaries.

Comment: One commenter urged CMS to provide guidance to Home Health Agencies on the use and role of physical therapists.

Response: Though we recognize the valuable role of physical therapy in the documentation and reporting of the new process measures as well as the provision of home health care to multiple patient populations including those with wounds, heart failure, and those in need of medication management, we hesitate to make recommendations on issues relating to staff use. Each HHA must review the needs of its patient population and evaluate the best way to achieve the appropriate level of care based on the competency of its staff.

Comment: Several commenters noted that their memberships believe that the OASIS–C instrument is an improvement over the existing OASIS–B1, but that many HHAs still have questions regarding the new tool and request information regarding training on its use.

Response: CMS believes that HHA's questions have been answered with the release of the OASIS–C Guidance Manual on October 9, 2009, the content of the OASIS–C presentation at the NAHC annual conference on October

10, 2009, and within the National Provider Calls that started on October 22, 2009.

Comment: Two commenters requested a delay in the public reporting of process measures. One requested delay until January 2012 to allow time for implementation, development of and risk adjustment models and staff education.

Response: Process measures are derived directly from OASIS–C data and by nature do not require risk adjustment. We began providing education on OASIS–C starting in October 2009.

Comment: One commenter requested a delay in the public reporting of process measures until June 1 (no year was included in the request).

Response: CMS plans that the process measures will be reported on Home Health Compare no earlier than October 2010.

Comment: Several commenters expressed concern with specifics related to the addition of the 13 new process measures. One commenter mentioned the lack of a timeframe for these measures and the perception that some measures (pneumococcal vaccine ever received and depression assessment conducted and influenza immunization received) are above and beyond what an agency is expected to do. One commenter recommended that questions related to ''potential medication issues identified'' and ''timely physician contact'' should not be included in public reporting since the outcome of those measures is largely determined by physician response.

Response: We believe strongly that the addition of process measures will enhance the HHAs' ability to improve the quality of care provided to beneficiaries. Process measures assess adherence to recommendations for clinical practice based on evidence or consensus. Measures based on data items that align with those used across other provider settings (such as pneumonia vaccine received) will promote systematic use of evidence-based practices with the aim of improving population health. To a greater extent than outcome measures, process measures can identify specific areas of care that may require improvement and give credit for good care provision. Data related to the process measures will be collected in the OASIS–C instrument beginning January 1, 2010 and the first reports on process measures are projected to be available to agencies in September 2010.

Comment: One commenter requested definitions of various terms used within the process measure descriptions.

Response: The OASIS–C Guidance Manual contains detailed information for the clinician in order to be able to respond to these items accurately.

- ''Short-term episode of care'': Implementation process measures report whether a care process was ''implemented since the last OASIS assessment''. These measures will be calculated separately for short-term episodes and long-term episodes. Short-term episodes are those in which the time frame from Start of care (SOC)/Resumption of Care (ROC) to Transfer (TRF)/Discharge (DC) is less than or equal to 60 days (and DO NOT contain a 60-day follow-up assessment). Long-term episodes are those in which the time frame from SOC/ROC to TRF/DC is longer than 60 days (and DO contain a 60-day follow-up assessment). In response to industry and NQF concerns that measures might not accurately reflect care for longer stay patients, episodes that exceed 60 days will not be included in publicly reported measures on implementation of evidence based practices.
- The phrase ''at start of episode'' does not refer to payment episodes and does not mean that this information will be collected and reported for each 60-day episode. The phrase means that the measure reports on best care practices that occur when a patient is admitted to home care. It is used to distinguish this measure from others that report on best practices that are implemented over the course of the home health stay (rather than at the time of home health admission) and are collected at transfer or discharge.
- ''Timely physician contact'' is defined as communication to the physician within one calendar day of the assessment by telephone, voicemail, electronic means, fax, or any other means that appropriately conveys the message of patient status.
- ''High risk medications'' are defined as those identified by quality organizations (Institute for Safe Medication Practices, Joint Commission, *etc.*) as having considerable potential for causing significant patient harm when they are used erroneously.
- In the OASIS–C Guidance Manual, clinically significant medication issues are defined as those that, in the care provider's clinical judgment, pose an actual or potential threat to patient health and safety, such as drug reactions, ineffective drug therapy, side effects, drug interactions, duplicate therapy, medication omissions, dosage errors, or non-adherence to prescribed medication regimen. Potential clinically significant medication issues include adverse reactions to medications (for example, rash), ineffective drug therapy (for example, analgesic that does not reduce pain), side effects (for example, potential bleeding from an anticoagulant), drug interactions (for example, serious drug-drug, drug-food and drug-disease interactions), duplicate therapy (for example, generic name and brand name drugs that are equivalent both prescribed), omissions (missing drugs from an ordered regimen), dosage errors (for example, either too high or too low), noncompliance (for example, regardless of whether the noncompliance is purposeful or accidental) or impairment or decline in an individual's mental or physical condition or functional or psychosocial status.

Comment: One commenter expressed concern with our proposal (set out at 74 FR 40960) regarding home health care quality improvement. We proposed to ''reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements.'' The commenter thought this process was new and requested that it be defined in more detail.

Response: This proposal is not new. Identical language was proposed in our May 4, 2007, CY 2008 HH PPS proposed rule (72 FR 25450) and in our CY 2009 HH PPS update notice (73 FR 65356). These proposals were subsequently implemented. Details regarding the process are available in the Medicare Claims Processing Manual, Chapter 10, section 120.

Comment: One commenter was concerned that pay for performance does not differentiate between traditional Medicare patients and those participating in waiver programs. Waiver patients have long-term chronic needs, unlikely to be shown in discharge data, or to improve in the same manner as traditional patients with short-term needs and expectations for recovery.

Response: We thank the commenter for the comment on this topic, and will consider his concerns related to differences in outcomes for dually eligible waiver patients as plans for pay for performance are developed.

Reporting of Home Health Care Quality Data Through CAHPS Survey

In the Home Health Prospective Payment System Rate Update for Calendar Year 2010 (August 13, 2009), we proposed to expand the home health quality measures reporting requirements to include the CAHPS® Home Health Care (HHCAHPS) Survey, as initially discussed in the May 4, 2007 proposed rule (72 FR 25356, 25452) and in the November 3, 2008 Notice (73 FR 65357,

65358). As part of the U.S. Department of Health and Human Services (DHHS) Transparency Initiative, we proposed to implement 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) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program. The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The HHCAHPS survey presents 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 home health agencies (HHAs).

In this Final Rule, we intend to move forward with the implementation of the HHCAHPS. However, we intend to link the survey to the CY 2012 payment update rather than to the CY 2011 payment update. We still intend to implement the survey on a voluntary basis beginning in October 2009.

Background and Description of the HHCAHPS

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

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

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

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

1. Patient care;
2. Communications between providers and patients; or
3. Specific care issues (medications, home safety and pain). There are also two global ratings; the first rating asks the patient to assess the care given by the HHA's care providers, and the second asks the patient about his/her willingness to recommend the HHA to family and friends.

There are two options for administering the HHCAHPS survey. The agency can choose to administer the existing HHCAHPS survey, or the HHA can integrate additional questions within the HHCAHPS survey. If an agency chooses to implement an integrated survey, the core questions from the HHCAHPS survey (questions 1 through 25) must be placed before any specific/supplemental questions that the home health agency wishes to add to the survey. Questions 26 through 34 (the ''About You'' survey questions) must be administered as a unit—although they may be placed either before or after any supplemental questions that the HHA wishes to add to the HHCAHPS survey. If no HHA-specific questions are to be added to the HHCAHPS survey, the ''About You'' questions should follow the core questions (numbered 1 through 25) on the HHCAHPS survey. In addition, there are nine optional supplemental HHCAHPS questions that are available for HHAs to use (in addition to the 34-item HHCAHPS survey). These optional supplemental HHCAHPS questions will not be publicly reported and are not required. The supplemental questions are listed in the Protocols and Guidelines Manual available at *https://www.homehealthcahps.org*.

The survey is currently available in both English and Spanish translations. We proposed that HHAs and their survey vendors will not be permitted to translate the HHCAHPS survey into any other languages on their own. However, it was proposed that CMS will provide additional translations of the survey over time. The Web site *https://www.homehealthcahps.org* will provide information about the subsequent availability of additional translations. In the proposed rule, we asked for suggestions for any additional language translations. Such suggestions should be submitted online to the HHCAHPS Survey Coordination Team, at *HHCAHPS@rti.org*.

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

The following types of home health care patients were proposed as eligible to participate in the HHCAHPS survey:

➢ Current or discharged patients who had at least one skilled care home health visit at any time during the sample month;

➢ Patients who were at least 18 years of age at any time during the sample period, and are believed to be alive;

➢ Patients who received *at least two skilled care visits* from HHA personnel during a 60-day look-back period. (Note that the 60-day look-back period is defined as the 60-day period prior to and including the last day in the sample month);

➢ Patients who have not been selected for the monthly sample during any month in the current quarter or during the 5 months immediately prior to the sample month;

➢ Patients who are not currently receiving hospice care;

➢ Patients who do not have ''maternity'' as the primary reason for receiving home health care; and

Patients who have not requested ''no publicity status.''

To collect and submit HHCAHPS data to CMS, Medicare-certified agencies will need to contract with an approved HHCAHPS survey vendor. Beginning in summer 2009, interested vendors applied to become approved HHCAHPS vendors. The application process was (and still is) delineated online at *https://www.homehealthcahps.org*. Vendors are required to attend training conducted by CMS and the HHCAHPS Survey Coordination Team, and to pass a post-training certification test.

Home health agencies that are interested in participating in the HHCAHPS survey may do so on a voluntary basis beginning in October 2009. Such agencies must select a vendor from the list of HHCAHPS approved survey vendors. This listing was made available on the Web site *https://www.homehealthcahps.org* on September 14, 2009. The listing will be updated on an ongoing basis to reflect the current approved list of survey vendors.

Participation Requirements for CY 2011: The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey

In the proposed rule, we proposed that beginning in the first quarter of CY 2010, all Medicare-certified home health agencies would begin to collect the CAHPS® Home Health Care (HHCAHPS) survey data in accordance with the Protocols and Guidelines Manual located on the HHCAHPS Web site *https://www.homehealthcahps.org*. Home health agencies would contract with approved HHCAHPS survey vendors (posted on *https://www.homehealthcahps.org*) that are to conduct the survey. We proposed that participating home health agencies would conduct a dry run of the survey for at least one month in the first quarter of 2010 (January, and/or February, and/or March 2010), and submit the dry run data to the Home Health CAHPS® Data Center by 11:59 p.m. EST on June 23, 2010. The dry run data would not be publicly reported on the CMS Home Health Compare Web site. This dry run would provide an opportunity for vendors and HHAs to acquire first-hand experience with data collection, including sampling and data submission to the Home Health CAHPS® Data Center, with no public reporting of the results. We proposed that all Medicare-certified home health agencies continuously collect HHCAHPS survey data every quarter beginning in the second quarter (April, May and June) of 2010, and submit these data for the second quarter of 2010 to the Home Health CAHPS® Data Center by 11:59 p.m. EST on September 22, 2010. We proposed that these data submission deadlines be firm (that is, there would be no late submissions allowed).

Medicare-certified HHAs would need to provide their respective survey vendors with information about their survey-eligible patients (either current or discharged) every month in accordance with the Protocols and Guidelines Manual posted on *https://www.homehealthcahps.org*. Details about selecting the HHA sample are also delineated in the Protocols and Guidelines Manual.

In the proposed rule, we proposed that the HHCAHPS survey data be submitted and analyzed quarterly, and that the sample selection and data collection occur on a monthly basis. HHAs would target 300 HHCAHPS survey completes annually. Smaller agencies that were unable to reach 300 survey completes by sampling would survey all HHCAHPS eligible patients. We proposed that survey vendors initiate the survey for each monthly sample within 3 weeks after the end of the sample month. We proposed that all data collection for each monthly sample be completed within 6 weeks (42 days) after data collection began. We have approved three modes of the survey to be used: mail only, telephone only, and mail with telephone follow-up (the ''mixed mode''). We proposed that for mail-only and mixed-mode surveys, data collection for a monthly sample would end 6 weeks after the first questionnaire was mailed. We proposed that for telephone-only surveys, data collection would end 6 weeks following the first telephone attempt.

In the proposed rule we wrote that we were aware that there was a wide variation in the size of Medicare-certified home health agencies. We proposed that the requirement to collect HHCAHPS survey data be waived for agencies that served fewer than 60 HHCAHPS eligible patients annually. The HHCAHPS eligible, unduplicated patient counts for the period of October 1 through September 30 for a given year would be used to determine if the HHA had to participate in the HHCAHPS survey in the next calendar year.

We also proposed that newly Medicare-certified home health agencies (that is, those certified on or after January 1, 2010 for payments to be made in CY 2011) be excluded from the HHCAHPS reporting requirement for the first year, as data submission and analysis would not be possible for an agency this late in the reporting period.

In the proposed rule, we strongly recommended that home health agencies participating in the HHCAHPS survey promptly review the required Data Submission Summary Reports that are described in the Protocols and Guidelines Manual posted on *https://www.homehealthcahps.org*. These reports will enable the home health agency to ensure that its survey vendor has submitted their data on time, and that the data have been accepted/received by the Home Health CAHPS® Data Center. We received no comments on this proposal, and are finalizing it as proposed.

Oversight Activities: The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey

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

- Organizational chart;
- Work plan for survey implementation;
- Description of survey procedures and quality controls;
- Quality assurance oversight of on-site work and of all subcontractors work; and
- Confidentiality/Privacy and Security procedures in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

As part of the oversight activities the HHCAHPS Survey Coordination Team would conduct on-site visits and/or conference calls. The HHCAHPS Survey Coordination Team would review the survey vendor's survey systems, and would assess administration protocols based on the Protocols and Guidelines Manual posted on *https://www.homehealthcahps.org*. We proposed that all materials relevant to survey administration would be subject to review. The proposed systems and program review would include but not be limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) data receipt, entry and storage facilities; and (d) written documentation of survey processes. Organizations would be given a defined time period in which to correct any problems and provide follow-up documentation of corrections for review. Survey vendors would be subject to follow-up site visits as needed.

We did not receive any comments regarding the proposed oversight activities and therefore, the proposed recommendations are considered to be final for this rule.

For Further Information on the HHCAHPS Survey

It is strongly recommended that all home health care agencies participating in the HHCAHPS survey regularly check

the Web site, *https://www.homehealthcahps.org* for program updates and information.

We proposed that all HHAs, unless covered by specific exclusions, meet the quality reporting requirements or be subject to a 2 percent reduction in the home health market basket percentage increase in accordance with section 1895(b)(3)(B)(v)(I) of the Act. A reconsideration and appeals process is being developed for HHAs who fail to meet the HHCAHPS reporting requirements. We proposed that these procedures would be detailed in the proposed CY 2012 home health payment rule, the period for which HHCAHPS will be linked to the home health market basket percentage increase.

Comment: We received a comment endorsing the proposed addition of the HHCAHPS patient perspectives of care survey, stating that it would be a useful supplement to existing performance measures.

Response: We appreciate this comment in support of adding the Home Health Care CAHPS (HHCAHPS) measures to the quality reporting program of the agency.

Comment: We received comments that HHCAHPS needs to be field-tested and the survey results need to be statistically reliable before such results are incorporated into quality reports, published on Home Health Compare, or counted in the consideration of the annual payment update for home health agencies.

Response: The Home Health Care CAHPS has been field-tested by AHRQ and the CAHPS grantees and the final survey is currently being used in a national, randomized mode experiment. A rigorous, scientific process was used in the development of the survey, including: a public call for measures; literature reviews; focus groups with home health patients; cognitive interviews with home health patients; stakeholder input; public response to **Federal Register** notices; and a field test.

Comment: We received feedback from commenters asking how HHCAHPS would be adjusted to account for variation in quality scores which is unrelated to agency behavior. One commenter noted that this would require matching of demographic and insurance data into a risk adjustment methodology. The commenter asked CMS to articulate how this adjustment will be achieved to prevent the release of spurious quality measures.

Response: We appreciate this feedback and would like to emphasize that from the very beginning of the planning for HHCAHPS, the prevention of spurious variables on the data was viewed as essential in the implementation of HHCAHPS. To further achieve this goal, we have additionally revised our protocols for the HHCAHPS based on comments that were sent to us. We are now including only Medicare and/or Medicaid patients in the HHCAHPS survey. For public reporting of the data, the data will be adjusted for mode of survey administration. The HHCAHPS measures will also be adjusted for patient mix. Patient-mix adjustments are made when certain patient characteristics that are beyond home health agencies' control impact how a patient responds to the survey. The patient-mix characteristics that have been identified for possible inclusion cover variables such as overall health status, diagnosis information, age, education, managed care indicator, whether the patient lives alone, and insurance coverage. Although the patient-mix adjusters included in the model are constant over time, the exact values of patient-mix adjustment coefficients are re-estimated each reporting period based on the empirical relationship observed between the patient-mix adjustment variables and HHCAHPS outcomes in that period.

Comment: We received comments that the HHCAHPS survey is too long. These commenters mentioned that the rates of completion of consumer satisfaction surveys are typically low, particularly when the instrument is long.

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

Comment: We received feedback from a commenter concerned that many HHA patients were not sufficiently educated to interpret the HHCAHPS correctly.

Response: We appreciate the sensitivity to the home health patients by asking about the readability of the HHCAHPS survey. The Flesch-Kincaid reading test showed that the HHCAHPS survey is at less than a seventh grade level. More importantly though, if patients are unable to answer the survey due to decreased capacities, a family or friend may assist the patient and answer the questions on behalf of the selected home health patient in the HHCAHPS home health agency sample.

Comment: We received comments asking how the HHCAHPS survey would be administered to patients suffering from dementia or psychiatric disorders.

Response: We appreciate comments sensitive to concerns about how HHCAHPS would be administered to patients suffering from dementia, or other disorders that might present challenges to respondents. Early on, we recognized the importance of allowing proxy respondents for this population even though proxy respondents are not always used in other CAHPS surveys. Proxy respondents answer the HHCAHPS survey on behalf of the patient respondent. We analyzed the field test data and found that proxy respondents do not respond differently from home health patients; thus, proxy respondents (that is, family members) are allowed. However, home health agency staff cannot serve as proxy respondents for patients.

Comment: We received feedback from one commenter that the existing survey timelines could result in patients being surveyed more than 60 days after their home health services ended, resulting in an inability to recall or evaluate services accurately.

Response: We appreciate this comment concerning surveying patients too long after they received services. We received comments from the home health agencies in our mode experiment that the earliest that they can deliver a patient list from the end of the month is about two weeks after the close of the month. Therefore, we have emphasized to the HHAs to send their patient lists to their respective vendors in time to begin data collection within 21 days after the close of any month. In most data collection scenarios, we believe that patients will be surveyed within 60 days from the time that they last received services from the home health agency. In certain circumstances, it may be that patients will be surveyed later than 60 days if they were seen the very beginning of the sample month and do not respond to the initial mail or telephone attempts. Overall, the goal of the data collection process is to survey the patients as soon as possible.

Comment: We received comments that there is a need for additional

language translations of the HHCAHPS besides English and Spanish. Several commenters mentioned the difficulties in implementing HHCAHPS because their agencies have few patients who speak either English or Spanish.

Response: We appreciate these concerns regarding the need for additional language translations and strongly encourage that these suggestions and specific requests be submitted as soon as possible to the HHCAHPS Survey Coordination Team at *HHCAHPS@rti.org.* Currently, CMS is creating a Chinese translation of the questionnaire and will produce additional translations in the coming year. CMS is not allowing vendors or individual HHAs to independently translate the survey into other languages on their own because of the need to assure comparable (if not identical) wording in every language, and thus ensure comparability of the survey data on a national basis.

Comment: We received several comments about how we chose the particular criteria on who is eligible/ineligible to participate in the survey.

Response: Based on input received through stakeholder meetings, AHRQ and CMS agreed that patients 18 and older needed to have 2 or more skilled visits in order to evaluate an agency's care. Additionally, maternity and hospice patients were excluded due to (1) the unique circumstances surrounding maternity care; and (2) the sensitivity associated with surveying hospice patients.

Comment: We received several comments concerning the inclusion of all patients, rather than limiting the survey to Medicare and/or Medicaid patients only. Commenters were concerned about the burden and validity of including non-Medicare or non-Medicaid patients as respondents.

Response: In this Final Rule we are recommending that the submission of HHCAHPS data be initially applied to Medicare and Medicaid patients only. Only Medicare and/or Medicaid patients are included in the HHCAHPS survey. All other eligibility criteria are being implemented as proposed.

Comment: We received comments asking why Home Health Agencies cannot conduct the HHCAHPS survey themselves (that is, self-administer the survey).

Response: Agencies are not allowed to conduct the survey on their own. Since many patients have a continuing relationship with their home health agency, we believe that an independent third party will be better able to solicit an unbiased response. Since they receive care in their homes, this population is particularly vulnerable and dependent upon their home health agency caregivers.

Comment: We received a comment asking CMS to clarify what oversight would occur regarding how agencies compile their patient lists and submit them to vendors.

Response: We thank the commenter for this inquiry and respond that we will be conducting oversight activities for the HHCAHPS vendors. As part of the oversight activities, we will monitor information about the number of patients eligible per month and may ask the vendor to provide sampling frame counts for a sample of agencies. If we are seeing unusual numbers of eligible patients counts compared against OASIS counts, we may work with the vendor and agency to determine if there are any systematic issues.

Comment: We received comments concerning the costs involved in contracting with an approved Home Health Care CAHPS vendor to collect and submit data. These costs represent an additional expenditure for agencies without additional compensation from CMS. These commenters stated vendor cost estimates have been provided, ranging anywhere from $5 per completed survey, up to $9,000 a year.

Response: We recognize that vendors will charge different amounts for the survey, and highly recommend that home health agencies ''shop around'' for the best value for their agency. The vendor list is available on *www.homehealthcahps.org.* Currently, 34 vendors have been approved to conduct the survey and additional vendors will be approved in the coming months. Therefore, for the final rule, only HHCAHPS-approved vendors may be used to conduct the HHCAHPS survey for participating home health agencies.

Comment: We received multiple comments about cost to the HHAs, and burden to the HHAs. We received feedback from one commenter who wrote that the HHCAHPS implementation process has not been well explained or thought through in terms of impacts on agencies; a number of commenters were concerned about the financial burden, particularly when reimbursements are decreasing. Another felt that software reprogramming costs and fees were not accurate in the burden estimates. Another commenter asked that CMS clarify whether CMS or HHAs will be paying vendors for their services. A number of commenters wrote that a policy which imposes a mandatory requirement but makes non-compliance subject to a penalty should be funded by CMS. Another commenter asked that we cap the amount that vendors would charge HHAs and allow HHAs to claim the cost as allowable on their cost reports.

Response: We are fully appreciative of the comments concerning cost burdens to the HHAs with the implementation of HHCAHPS. We believe that home health agencies should ''shop around'' for the best value by researching as many vendors as possible that are listed on the vendor list on *http://www.homehealthcahps.org.* We are confident that there are reasonable choices for the HHAs with the current list of vendors. We have limited the initial data collection to Medicare and/or Medicaid patients to reduce the burden of providing administrative data on private pay patients. We will also accept V codes instead of ICD–9 codes if the agency does not have ICD–9 codes for particular patients. All of the administrative variables should be available on OASIS and should require minimal reprogramming for the HHAs to provide patient information to their survey vendors. HHAs will be paying vendors for data collection and processing services and we will be paying for training, technical assistance, oversight of vendors, and data analysis of the HHCAHPS data. In response to the comment that this is a mandatory requirement that makes non-compliance subject to a penalty, we respond that the expanded requirements concerning the collection of quality data were stated in the CY 2008 Home Health Payment Rule and in the CY 2009 Home Health Notice of October 31, 2008. The expanded requirements concerning quality data for home health agencies were also stated in the Deficit Reduction Act. The collection of quality data for similar CAHPS surveys, such as the Hospital CAHPS survey, follow the same model wherein the health care providers pay the approved survey vendors for the data collection costs and we pay for the training, technical assistance, oversight of vendors, and data analysis costs. HHAs are strongly encouraged to report their respective HHCAHPS cost on their cost reports but should note that these costs are not reimbursable under the HH PPS.

Comment: We received comments asking whether HHCAHPS participation is really a voluntary program.

Response: The first year of the HHCAHPS is entirely voluntary. Once data collection is tied to the annual payment update for CY 2012 (voluntary data collection begins October 2010), agencies may choose to participate. Moreover, agencies may still choose *not* to participate in the survey if they believe that the costs of participating

will exceed the two percent reduction of the full annual payment update they would otherwise receive.

Comment: While commenters were generally supportive of the survey, and of quality improvement measures in home health, many requested a delay in the implementation of the survey. Commenters were concerned about implementing this new requirement at the same time as the rollout for OASIS–C. They wanted home health agencies to have additional time to select a vendor to conduct the survey for them. Commenters were concerned about not accounting for this expense in their 2010 budgets, and wanted additional time to evaluate and pilot the survey on their own.

Response: CMS has carefully considered the comments it received, and is delaying the linkage of HHCAHPS data to the quality reporting requirements for the annual payment update by 6 months. This will allow home health agencies to first fully implement OASIS–C before being required to implement the HHCAHPS survey for payment considerations. As such, agencies will be required to do a dry run for at least one month in third quarter CY 2010, and to begin data collection on an ongoing basis in October 2010. With this change, HHAs will be required to submit dry run data from the third quarter of CY 2010 to the Home Health CAHPS Data Center by 11:59 p.m. EST on January 21, 2011. Similarly, HHAs will be required to submit data for the fourth quarter of CY 2010 to the Home Health CAHPS Data Center by 11:59 p.m. on April 21, 2011. With this delay, HHCAHPS will be a requirement for agencies to receive their full 2012 annual payment update.

As a result of this rule's final provision to tie the HHCAHPS to the CY 2012 annual payment update (rather than to the CY 2011 annual payment update), home health agencies certified on or after April 1, 2011 will be excluded from the HHCAHPS reporting requirement for CY 2012 as data submission and analysis will not be possible for an agency this late in the CY 2012 reporting period. Agencies should begin HHCAHPS data collection as soon as possible to meet HHCAPS reporting requirements for future years. Additionally, by June 16, 2010, HHAs need to provide CMS with patient counts for the period of April 1, 2009 through March 31, 2010. CMS will post a form that the HHAs will use to submit their patient counts via the Web site, *http://www.homehealthcahps.org.* This requirement pertains only to Medicare-certified HHAs with fewer than 60 eligible, unduplicated patients for that time period. Such agencies would be exempt from conducting the HHCAHPS survey for the annual payment update in CY 2012. Agencies that have fewer than 60 eligible, unduplicated patients would be exempt from data collection from third quarter CY 2010 through second quarter CY 2011.

Comment: We received comments about the HHCAHPS data submission requirements for reporting ICD–9 codes for patient diagnosis. It was proposed in the Protocols and Guidelines Manual and also in CMS training that ICD–9 codes be used in patient mix adjustment to ensure the HHCAHPS results are comparable across agencies. However, commenters wrote that over 40 percent of home health agencies use V-codes to indicate a patient's primary diagnosis. Home health agencies however, are in agreement that V codes do not accurately reflect the medical conditions of their patient population.

Response: Based on feedback from the proposed rule, we have modified the specifications to allow for the submission of V codes if those are the only available data. However, we strongly encourage the submission of ICD–9 codes if feasible. The reason for collecting diagnosis codes that are not V codes is to distinguish patients who, because of their underlying condition, may have very different attitudes about the health care they receive and who also may respond very differently to the questions on the HHCAHPS. Prior research has shown that patients rate the care they receive differently based on their characteristics. For example, older patients tend to rate more favorably than younger patients, but sicker patients tend to rate less favorably than relatively healthier patients. Consider the case in which two patients are coded with one of the V57 rehabilitation codes; however, one has had knee surgery and the other has had a stroke. These two patients will potentially have different perspectives and opinions about the home health care they receive, and these perspectives will affect how they respond to the HHCAHPS survey items. The V code in this example does not indicate the severity of the illness/condition. For this reason, we urge survey vendors to provide ICD–9 codes whenever possible, so that survey results can be statistically adjusted to account for any differences in responses based on patient characteristics. Therefore, for the final rule, we will allow V codes if those are the only available data.

Comment: We received feedback from a commenter that the requirements for HHCAHPS include reporting ADL scores from OASIS, but OASIS is not required for non-Medicare, non-Medicaid patients. HHAs that do perform an OASIS assessment on these patients do not enter the information into their electronic files since HHAs are prohibited from reporting these data to the State repository.

Response: We are appreciative of this comment and for the final rule have limited data collection to Medicare and/or Medicaid patients. In addition, we are also allowing V codes if ICD–9 data are unavailable for the HHCAHPS patients.

Comment: We received a comment suggesting that we reevaluate patient data submission requirements, and streamline the amount of information essential to the accurate reporting of patient experiences.

Response: We appreciate this comment concerning a reevaluation of the patient data submission requirements for HHCAHPS. Accordingly, we have revised the data submission requirements with two significant changes in this final rule. The first change is that only Medicare and/or Medicaid patients are in the HHCAHPS. The second change is that HHAs may submit V codes if ICD–9 codes are unavailable.

Comment: We received several comments concerning the survey modes and the need for 300 completed surveys a year. We received several comments that HHCAHPS should only be administered by mail mode to ensure comparability. Similarly, we received requests that HHCAHPS be only available in the telephone mode for comparability. Finally, we received comments that only one survey mode should be accepted for use for HHCAHPS, no matter what the mode choice was, for comparability across all agencies nationally.

Response: We appreciate these comments because they are all related to the same goal to ensure comparability of the survey results for all participating HHAs. HHCAHPS, as a part of the CAHPS program, is always striving to ensure comparability in all steps of the survey implementation and analysis of results. We realized that to limit the survey mode to only one type (for example, telephone only) could be limiting the HHAs in choosing survey vendors.

We dealt with a similar issue with the Hospital CAHPS survey, for which several modes of administration were ultimately permitted. While patient responses did vary based on the survey mode employed, it was possible to adjust for these differences statistically. We are therefore conducting a randomized mode experiment to test the

effect of using three data collection modes: mail only, telephone only, and mixed mode (mail with telephone follow-up of non-respondents). If the mode experiment suggests that the method of data collection has a significant impact on the survey responses, then we will use the results from the mode experiment to make appropriate adjustments in the reporting of the survey responses. When the mode experiment is concluded and all results, conclusions and recommendations are available, the results as well as the adjustments will be posted on *http://www.homehealthcahps.org,* the official Web site of the Home Health Care CAHPS survey. In the meantime, for the final rule, the HHCAHPS will allow three survey modes as proposed.

Comment: We received comments that questioned the advisability of requiring a total of 300 completed surveys since this number will have varying statistical validity for small versus large agencies. Further, HHAs serving populations that tend to be poor respondents will be unable to meet this total number, particularly if the agencies themselves are small in size. In addition, commenters were concerned about the validity of data comparing small agencies (that may need to survey 100 percent of the patients in order to meet the required target) with large agencies (which may be able to survey as few as 1 percent of their patients and reach the target).

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

Comment: We received feedback from a commenter that suggested that CMS base compliance with the requirement on whether HHAs submitted appropriate numbers of patient files for their size, rather than on the number of patients that responded to surveys.

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

Summary of Final Rule Changes for HHCAHPS

For this final rule, we are adopting three changes to the previously proposed provisions for HHCAHPS. The first change is the delay in the HHCAHPS linkage to the annual payment update, from CY 2011 to CY 2012. This delay means that home health agencies will need to conduct a dry run for at least one month in the third quarter 2010, and continuously collect survey data beginning in the fourth quarter 2010 and moving forward. HHAs are urged to note the revised dates in this Final Rule and to routinely check the Web site *http://www.homehealthcahps.org* for the key dates. The second change concerns the patients eligible for the survey: only Medicare and/or Medicaid patients will be eligible to take the HHCAHPS survey. The third change is that V codes may be submitted if ICD–9 codes are unavailable. Home Health Compare will be updated to reflect the addition of HHCAHPS to the quality reporting requirements.

3. Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require that we adjust the HH PPS payment rates to account for differences in area wage levels, using a wage index that we find appropriate. Since the inception of the HH PPS, we have used hospital wage data in developing a wage index to be applied to HHAs.

In the CY 2010 proposed rule, we proposed to continue that practice, as we continue to believe that using the pre-floor, pre-reclassified hospital inpatient wage index is appropriate and reasonable for the HH PPS. As explained in the update notice for CY 2009 (73 FR 65359), the HH PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting.

We apply the appropriate wage index value to the labor portion (77.082 percent) 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).

In the HH PPS final rule for CY 2006 (70 FR 68138, November 9, 2005), we adopted the changes discussed in the Office of Management and Budget (OMB) Bulletin No. 03–04 (June 6, 2003), available online at *http://www.whitehouse.gov/omb/bulletins/b03-04.html*, which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In addition, OMB published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles.

In adopting the OMB Core-Based Statistical Area (CBSA) geographic designations, we provided for a 1-year transition with a blended wage index for all providers. For CY 2006, the wage index for each provider consisted of a blend of 50 percent of the CY 2006 MSA-based wage index and 50 percent of the CY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the CY 2006 HH PPS transition wage index. As discussed in the HH PPS final rule for CY 2006 (70 FR 68138, November 9, 2005), subsequent to the expiration of the 1-year transition on December 31, 2006, we use the full CBSA-based wage index values.

We continue to use the methodology discussed in the CY 2007 final rule (71 FR 65884, November 9, 2006) to address those geographic areas in which there are no hospitals and, thus, no hospital wage data on which to base the calculation of the HH PPS wage index. For those areas, we use the average wage index from all contiguous CBSAs as a reasonable proxy. This methodology is used to calculate the wage index for rural Massachusetts. However, we do not apply this methodology to rural Puerto Rico due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005). For urban areas without specific hospital wage data, we use the average wage indexes of all urban areas within the State to serve as a reasonable proxy for the wage index of that that urban CBSA. The only urban area without wage data is Hinesville-Fort Stewart, Georgia (CBSA 25980).

On November 20, 2008, OMB issued Bulletin No. 09–01 located at Web address *http://www.whitehouse.gov/omb/bulletins/fy2009/09-01.pdf.* This bulletin highlights three geographic areas that were previously classified as Micropolitan Statistical Areas but now

qualify as Metropolitan Statistical Areas. The three areas are: (1) CBSA 16020, Cape Girardeau-Jackson, MO–IL (this includes Alexander County in Illinois and Bollinger and Cape Girardeau Counties in Missouri); (2) CBSA 31740, Manhattan, KS (this includes Geary, Pottawatomie, and Riley Counties in Kansas); and (3) CBSA 31860, Mankato-North Mankato, MN (this includes Blue Earth and Nicollet Counties in Minnesota).

The comments that we received on the wage index adjustment to the HH PPS rates, and our responses to those comments, appear below.

Comment: A commenter requested that CMS develop an industry specific (HH specific) wage index.

Response: Our previous attempts at either proposing or developing a home health specific wage index were not well received by commenters or the industry. Generally, the volatility of the home health wage data and the resources needed to audit and verify those data make it difficult to ensure that such a wage index accurately reflects the wages and wage-related costs applicable to the furnishing of services. We believe it is important that a HH specific wage index be more reflective of the wages and salaries paid in a specific area, be based upon stable data sources, and significantly improve our ability to determine HH payments without being overly burdensome.

Comment: As an alternative to the rural floor, one commenter suggested we adjust for population density during calculation of the labor portion of payments to account for the increased costs of providing services in rural areas.

Response: The proposal of utilizing a population density adjustment is suggestive of a rural add-on. The HH PPS has utilized rural add-ons during various time periods since its inception. However, rural add-ons must be legislated. The last rural add-on, which was mandated by section 5201(b) of the Deficit Reduction Act (DRA), expired in early CY 2007.

Comment: A commenter wrote that it was unfair for HHAs to be tied to erroneous hospital data with no recourse.

Response: CMS utilizes efficient means to ensure and review the accuracy of the hospital cost report 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 cost report data from hospitals paid under the hospital inpatient prospective payment system (IPPS). All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. 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 wages for the areas given.

Comment: A few commenters objected to our using CBSA area, which they stated creates arbitrary payment differences along CBSA borders, and exacerbate instability in the wage index.

Response: We believe that adjusting payments based on the CBSA areas is the best available method of compensating for differences in labor markets.

Comment: A few commenters suggested we establish limits on allowable annual changes in wage index values from one year to the next. One suggested spreading any wage index value changes greater than 2 percent over at least 2 years.

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: Several commenters asked CMS to allow HHAs to apply for the type of geographic reclassification that IPPS hospitals are provided. In addition, several commenters recommended establishing a rural floor.

Response: The commenters are referring to rural floor and geographic reclassification provisions in the IPPS which are only applicable to hospital payments. The rural floor provision is provided at section 4410 of Public Law 105–33 and is specific to hospitals. The reclassification provision provided at section 1886(d)(10) of the Act is also specific to hospitals. In its June 2007 report titled, ''Report to Congress: Promoting Greater Efficiency in Medicare'', MedPAC recommends that Congress ''repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems.'' We believe that adopting the IPPS wage index policies (such as reclassification or floor) would not be prudent at this time, because MedPAC suggests that the reclassification and exception policies in the IPPS wage index alter the wage index values for one-third of IPPS hospitals. In addition, MedPAC found that the exceptions may lead to anomalies in the wage index. By adopting the IPPS reclassification and exceptions at this time, the HH PPS wage index could become vulnerable to problems similar to those that MedPAC identified in their June 2007 Report to Congress. However, we will continue to review and consider MedPAC's recommendations on a refined alternative wage index methodology for the HH PPS in the future.

Comment: Several commenters recommended MedPAC's approach to the HH wage index outlined in its June 2007 report. This approach would use Bureau of Labor Statistics (BLS) data to provide more consistent values among neighboring markets and less year-to-year volatility in values. Additionally, the MedPAC methodology would utilize data that are available for all labor areas, eliminating the need to impute a wage index in areas with no hospital.

Response: In February 2008, CMS awarded a Task Order under its 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 in MedPAC's 2007 report to Congress. Part One 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*. We will continue monitoring wage index reform efforts and their potential influence on the HH PPS wage index.

Moreover, in light of all of the pending research and review of wage index issues in general, it would be premature at this time to initiate revisiting the use of CBSA labor market areas and review of a HH specific wage index.

Therefore, in this final rule, we will continue to use hospital wage data to calculate the HH PPS wage index adjustment, and are finalizing the wage index policies as discussed in the CY 2010 proposed rule (74 FR 40948–40982, August 13, 2009). Refer to Addenda A and B of this final rule for the wage index applicable to CY 2010 HH PPS payments.

4. CY 2010 Payment Update

a. National Standardized 60-Day Episode Rate

The CY 2010 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. We multiply the national 60-day episode rate by the patient's applicable case-mix weight. We divide the case-mix adjusted amount into a labor and non-labor portion. We multiply the labor portion by the applicable wage index based on the site of service of the beneficiary. We 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.

For CY 2010, we 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 will 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, as discussed in the CY 2008 HH PPS final rule with comment period. We update the LUPA add-on payment amount and the NRS conversion factor by the applicable home health market basket update of 2.0 percent for CY 2010.

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

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

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

b. Updated CY 2010 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2010 national standardized 60-day episode payment rates, we first look at the CY 2009 rates as a starting point. The CY 2009 national standardized 60-day episode payment rate is $2,271.92.

As discussed in section II.B., ''Outlier Policy'', of the CY 2010 proposed rule, and finalized in section II.A. of this final rule, in our final policy of targeting outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010, we are returning 2.5 percent back into the HH PPS rates, to include the national standardized 60-day episode payment rate. As such, to calculate the CY 2010 national standardized 60-day episode payment rate, we first increase the CY 2009 national standardized 60-day episode payment rate ($2,271.92) to adjust for the 5 percent originally set aside for outlier payments. We then reduce that adjusted payment amount by 2.5 percent, the final target percentage of outlier payments as a percentage of total HH PPS payment. Next, we update by the final CY 2010 home health market basket update percentage of 2.0 percent.

As previously discussed in section II.C., ''Case-Mix Measurement Analysis'', of the proposed rule, our updated analysis of the change in case-mix not due to an underlying change in patient health status reveals additional increase in nominal case-mix. As discussed, we are moving forward with our existing policy to reduce rates by 2.75 percent in CY 2010. Consequently, to calculate the CY 2010 national standardized 60-day episode payment rate, we then reduce the rate by 2.75 percent, for a final updated CY 2010 national standardized 60-day episode payment rate of $2,312.94. The final updated CY 2010 national standardized 60-day episode payment rate for an HHA that submits the required quality data is shown in Table 1. The final updated CY 2010 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data (home health market basket update of 2.0 percent is reduced by 2 percent) is shown in Table 2.

TABLE 1—NATIONAL STANDARDIZED 60-DAY EPISODE PAYMENT RATE UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2010, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

CY 2009 National standardized 60-day episode payment rate	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the home health market basket update (2.0 percent) [1]	Reduce by 2.75 percent for nominal change in case-mix	CY 2010 National standardized 60-day episode payment rate
$2,271.92	/ 0.95	× 0.975	× 1.020	× 0.9725	$2,312.94

[1] The estimated home health market basket update of 2.0 percent for CY 2010 is based on IHS Global Insight Inc., 3rd Qtr 2009 forecast with historical data through 2nd Qtr 2009.

TABLE 2—FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA; NATIONAL STANDARDIZED 60-DAY EPISODE PAYMENT RATE UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2010, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

Total CY 2009 National standardized 60-day episode payment rate	Adjusted to return the outlier funds, that paid for the original 5% target for outliers	Adjusted to account for the 2.5% outlier policy	Multiply by the home health market basket update (2.0 percent) [1] minus 2 percent for a 0.0 percent update	Reduce by 2.75 percent for nominal change in case-mix	CY 2010 National standardized 60-day episode payment rate for HHAs that do not submit required quality data
$2,271.92	/ 0.95	× 0.975	× 1.00	× 0.9725	$2,267.59

[1] The estimated home health market basket update of 2.0 percent for CY 2010 is based on IHS Global Insight Inc., 3rd Qtr 2009 forecast with historical data through 2nd Qtr 2009.

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

In calculating the CY 2010 national per-visit rates used to calculate payments for LUPA episodes and to compute the imputed costs in outlier calculations, we start with the CY 2009 national per-visit rates. We first adjust the CY 2009 national per-visit rates to adjust for the 5 percent originally set aside for outlier payments. We then reduce those national per-visit rates by 2.5 percent, the final target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the current CY 2010 home health market basket update percentage of 2.0 percent. National per-visit rates are not subjected to the 2.75 percent reduction related to the nominal increase in case-mix because they are per-visit rates and hence not case-mix adjusted. The final updated CY 2010 national per-visit rates per discipline are shown in Table 3.

TABLE 3—NATIONAL PER-VISIT RATES FOR LUPAS (NOT INCLUDING THE LUPA ADD-ON PAYMENT AMOUNT FOR A BENEFICIARY'S ONLY EPISODE OR THE INITIAL EPISODE IN A SEQUENCE OF ADJACENT EPISODES) AND OUTLIER CALCULATIONS UPDATED BY THE CY 2010 HOME HEALTH MARKET BASKET UPDATE, BEFORE WAGE INDEX ADJUSTMENT

Home health discipline type	CY 2009 Per-visit amounts per 60-day episode for LUPAs	Adjusted to return the outlier funds that paid for the original 5% target for outlier payments	Adjusted to account for the 2.5% outlier policy	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
				Multiply by the home health market basket update (2.0 percent) [1]	CY 2010 per-visit payment amount for HHAs that DO submit the required quality data	Multiply by the home health market basket update (2.0 percent) [1] minus 2 percent, for a 0 percent update	CY 2010 per-visit payment amount for HHAs that DO NOT submit the required quality data
Home Health Aide	$48.89	/ 0.95	× 0.975	× 1.02	$51.18	× 1.00	$50.18
Medical Social Services	173.05	/ 0.95	× 0.975	× 1.02	181.16	× 1.00	177.60
Occupational Therapy	118.83	/ 0.95	× 0.975	× 1.02	124.40	× 1.00	121.96
Physical Therapy	118.04	/ 0.95	× 0.975	× 1.02	123.57	× 1.00	121.15
Skilled Nursing	107.95	/ 0.95	× 0.975	× 1.02	113.01	× 1.00	110.79
Speech-Language Pathology	128.26	/ 0.95	× 0.975	× 1.02	134.27	× 1.00	131.64

[1] The proposed estimated home health market basket update of 2.0 percent for CY 2010 is based on IHS Global Insight Inc., 3rd Qtr 2009 forecast with historical data through 2nd Qtr 2009.

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 were adjusted by adding an additional amount to the LUPA payment before adjusting for area wage differences. As previously discussed, we are returning 2.5 percent back into the HH PPS rates, to include the LUPA add-on payment amount, as a result of our final policy to target outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010. As such, we first adjust the CY 2009 LUPA add-on payment amount to adjust for the 5 percent originally set aside for outlier payments. We then reduce that amount by 2.5 percent, the final target percentage of outlier payments as a percentage of total HH PPS payment. Next we updated by the current CY 2010 home health market basket update percentage of 2.0 percent. The LUPA add-on payment amount was not subject to the 2.75 percent reduction related to the nominal increase in case-mix because it is an add-on to the per-visit rates which are not case-mix adjusted.

The final updated CY 2010 LUPA add-on payment amount is shown in Table 4 below. Just as the standardized 60-day episode rate and the per-visit rates paid to HHAs that do not submit the required quality are reduced by 2 percent, the additional LUPA payment should be reduced by 2 percent also. In neither the CY 2008 nor the CY 2009

HH PPS rulemaking did we include such an adjustment to the LUPA add-on payment amount. For CY 2010, the add-on to the LUPA payment to HHAs that submit the required quality data will be updated by the full home health market basket update. The add-on to the LUPA payment to HHAs that do not submit the required quality data will be updated by the home health market basket update minus two percent.

TABLE 4—CY 2010 LUPA ADD-ON PAYMENT AMOUNTS

			For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
CY 2009 LUPA Add-on payment amount	Adjusted to return the outlier funds, that paid for the original 5% target for outliers	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the home health market basket update (2.0 percent) [1]	CY 2010 LUPA Add-on payment amount for HHAs that DO submit required quality data	Multiply by the home health market basket update (2.0 percent) [1] minus 2 percent, for a 0.0 percent update	CY 2010 LUPA Add-on payment amount for HHAs that DO NOT submit required quality data
$90.48	/ 0.95	× 0.975	× 1.02	$94.72	× 1.00	$92.86

[1] The proposed estimated home health market basket update of 2.0 percent for CY 2010 is based on IHS Global Insight Inc., 3rd Qtr 2009 forecast with historical data through 2nd Qtr 2009.

e. Non-Routine Medical Supply Conversion Factor Update

Payments for non-routine medical supplies (NRS) are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. We first adjust the CY 2009 NRS conversion factor ($52.39) to adjust for the 5 percent originally set aside for outlier payments. We then reduce that amount by 2.5 percent, the final target percentage of outlier payments as a percentage of total HH PPS payment.

Next we update by the current proposed CY 2010 home health market basket update percentage of 2.0 percent. Finally, we then reduce that adjusted payment amount by 2.75, to account for the increase in nominal case-mix. The final updated CY 2010 NRS conversion factor is shown in Table 5a below. The NRS conversion factor for CY 2009 was $52.39. For CY 2010, the NRS conversion factor is $53.34.

TABLE 5A

CY 2009 NRS conversion factor	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the 2.5% outlier policy	Multiply by the home health market basket update (2.0 percent)	Reduce by 2.75 percent for nominal change in case-mix	CY 2010 NRS conversion factor for HHAs that DO submit the required quality data
$52.39	/ 0.95	× 0.975	× 1.02	× 0.9725	$53.34

The payment amounts, using the above computed CY 2010 NRS conversion factor ($53.34), for the various severity levels based on the updated conversion factor are calculated in Table 5b.

TABLE 5B—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM

Severity level	Points (scoring)	Relative weight	NRS payment amount
1	0	0.2698	$14.39
2	1 to 14	0.9742	51.96
3	15 to 27	2.6712	142.48
4	28 to 48	3.9686	211.69
5	49 to 98	6.1198	326.43
6	99+	10.5254	561.42

For HHAs that do not submit the required quality data, we again begin with the CY 2009 NRS conversion factor. We first adjust the CY 2009 NRS conversion factor ($52.39) to adjust for the 5 percent originally set aside for outlier payments. We then reduce that amount by 2.5 percent, the final target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the current CY 2010 home health market basket update percentage of 2.0 percent minus 2 percent) for a 0.00 percent update. Finally, we then reduce that adjusted payment amount by 2.75, to account for the increase in nominal case-mix. The final updated CY 2010 NRS conversion factor for HHAs that do not submit quality data is shown in Table 6A below.

TABLE 6A—CY 2010 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2009 NRS Conversion Factor	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the proposed home health market basket update (2.0 percent) minus 2 percent for a 0.0 percent update	Reduce by 2.75 percent for nominal change in case-mix	CY 2010 NRS conversion factor for HHAs that DO NOT submit the required quality data
$52.39	/ 0.95	× 0.975	× 1.00	× 0.9725	$52.29

The payment amounts for the various severity levels based on the updated conversions factor, for HHAs that do not submit quality data, are calculated in Table 6B, below.

TABLE 6B—RELATIVE WEIGHTS FOR THE 6–SEVERITY FOR HHAS THAT DO NOT SUBMIT QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed NRS payment amount
1	0	0.2698	$14.11
2	1 to 14	0.9742	50.94
3	15 to 27	2.6712	139.68
4	28 to 48	3.9686	207.52
5	49 to 98	6.1198	320.00
6	99+	10.5254	550.37

D. OASIS Issues

1. HIPPS Code Reporting

In the proposed rule we clarified our policy regarding the submission of the Health Insurance Prospective Payment System (HIPPS) codes to CMS via OASIS. § 484.250 requires HHAs to submit to CMS the OASIS data described in § 484.55(b)(1) and § 484.55(d)(1) in order for CMS to administer the payment rate methodologies. Also, as described in § 484.20, HHAs must electronically report all OASIS data collected in accordance with § 484.55 as a condition of participation, and HHAs must encode and electronically transmit the completed OASIS assessment to CMS in the standard data format as described in § 484.20(d). For those OASIS assessments required for payment, the standard format which is electronically transmitted by the HHA to CMS includes a HIPPS code, generated by grouper software at the HHA. When an HHA electronically transmits OASIS assessments to CMS (via the State agency), the CMS OASIS submission system performs a validation check of the transmitted OASIS items, including the submitted HIPPS code. If the CMS OASIS submission system validation determines that the submitted HIPPS code is in error, it informs HHAs of that error via the Final Validation Report which is returned to HHA. The Final Validation Report will include the valid, CMS OASIS submission system calculated HIPPS code. We have become aware of a proliferation of incidents where the HIPPS code submitted to CMS on the OASIS does not match the HIPPS code, which is calculated by the CMS OASIS submission system. The HH PPS Grouper Software, which is used by the CMS OASIS submission system in its validation, is the official grouping software of the HH PPS, and thus the HIPPS code produced by the CMS OASIS submission system is the HIPPS code that should ultimately be billed on the claim. Consequently, in the interest of accurate coding and billing, we proposed that the HHA be required to ensure that the HIPPS code billed on the claim is consistent with that which CMS' OASIS submission system calculated. In the case where the Final Validation Report returns to the HHA a HIPPS code which is different than the HIPPS code submitted to CMS by the HHA on the OASIS, the HHA must ensure that the HIPPS code from the Final Validation report is the HIPPS code reported on the bill.

Comment: Commenters were supportive of our proposal to require that the OASIS HIPPS code match that on the claim. However, one commenter noted that some software cannot identify claims that need to have the HIPPS codes reconciled, and suggested we allow time for vendors to accommodate, and time for providers to develop internal procedures. This commenter also asked that we clarify in greater detail what is meant by non-compliance. If the proposal is finalized, and enforced on an individual claim basis, this commenter suggested that after a delay for systems changes, we allow for testing of individual claim edits by generating warning messages. The commenter suggested this occur during a trial period to give providers time to test out procedures and software.

Other commenters wrote that if we move toward requiring claim-by-claim verification of the HIPPS codes against the OASIS data repository, the system should be constructed to avoid delays in payment. One commenter stated that the proposed rule wasn't clear about when the trend toward incorrect HIPPS coding began. This commenter wrote that if it began with the 2008 refinement, did we consider factors outside of HHA control, such as the effect of item M0110, which impacts the HIPPS code. HHAs may not have enough information to answer M0110 at the start of the episode, but the FI may automatically change the HIPPS code due to more current information related to M0110 in CWF which was not available to the HHA at start of care. The commenter asks how we will ensure that the HIPPS codes match in this scenario, and how agency oversight would occur. Another commenter asked what the consequences would be if a few claims had minor discrepancies, and would like us to provide additional information on the implications and consequences of policy statements regarding the differences in HIPPS generated by OASIS and HIPPS on the claim.

Some commenters expressed concern that some vendor billing software used by HHAs is not currently able to identify situations where the HIPPS code submitted on claims needs to be reconciled to the HIPPS code calculated by State OASIS systems. The commenter requested that CMS allow additional time for vendors and HHAs to make changes to their software and that CMS systems generate warning messages during a trial period.

Response: HHAs do not necessarily need to change their software initially in order to comply with this requirement. If HIPPS codes generated by the HHA's software do not match the code calculated by State OASIS systems, the HHA currently receives a warning message alerting them to this problem. HHAs should use these warning messages as a trigger to correct any HIPPS code submitted for payment by either canceling and resubmitting any paid Request for Anticipated Payment (RAP) or adjusting any paid claim. Since canceling or adjusting claims are routine billing processes, we do not believe additional time is necessary to allow HHAs to prepare for them.

In the future, enforcement of this requirement may be implemented on a pre-payment basis. HHAs should seek to improve their compliance and their internal processes now in order to prepare for any future pre-payment requirement. Specific information about future enforcement mechanisms will be provided by Medicare program instructions with sufficient time for HHAs to prepare for them.

The information that highlighted the errors in HIPPS code reporting reflected all 2008 claims. However, the information compared the HIPPS codes the HHA initially submitted on claims with the HIPPS codes calculated by the State OASIS system for the same episode. Both the HHA and the State system were using the same M0110 information in their calculations, so subsequent changes in that information could not affect the results. CMS will consider the effect of M0110 information in any future enforcement mechanism.

As such, in the interest of accurate coding and billing, we are implementing the provision that the HHA be required to ensure that the HIPPS code billed on the claim is consistent with that which CMS' OASIS submission system calculated. In the case where the Final Validation Report returns to the HHA a HIPPS code which is different than the HIPPS code submitted to CMS by the HHA on the OASIS, the HHA must ensure that the HIPPS code from the Final Validation report is the HIPPS code reported on the bill.

2. OASIS Submission as a ''Condition of Payment''

Section 484.20 requires that HHAs must electronically report to CMS (via the State agency or OASIS contractor) all OASIS data collected in accordance with § 484.55 as a condition of participation. Additionally, § 484.250 requires that HHAs must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies. Building on the above clarification for HHAs to ensure the HIPPS code reported on the bill is consistent with that which CMS' OASIS submission system calculated, and in order to be consistent with § 484.250, in the proposed rule, we proposed to require the electronic reporting of OASIS to CMS as a condition of payment in § 484.210. Currently, as a requirement for pay for reporting, HHAs are required to submit quality data (that being OASIS data) in order to receive the full home health market basket update to the rates. The burden associated with the requirement for the HHA to submit the OASIS is currently accounted for under OMB# 0938–0761. Making OASIS submission a condition for payment is consistent with both OASIS submissions being a condition of participation and a requirement to receive full market basket updates under pay for reporting.

Comment: Several commenters supported our proposal to require OASIS reporting as a condition of payment, calling it an appropriate step toward ensuring agreement between the HHRG on OASIS and that reported on the claim. However, these commenters were confused because they wrote that the proposed regulatory language and the language in the current regulation are the same. They also requested that we clarify how the proposed change would affect current procedures for RAPs and claims submissions, saying that currently HHAs are required to have OASIS data ready for transmission before submitting a RAP, but are not required to have submitted OASIS.

Additionally, these commenters noted that compliance with 42 CFR 455.55(b)(1) and (d)(1) specifies that OASIS data submitted requires completion of the comprehensive assessment with OASIS within 5 days after the start of care and during the last 5 days of a prior episode for recertification. The commenter was concerned that the impact of the proposed change could preclude HHAs from receiving Medicare payment in all cases where OASIS was not completed within the 5-day timeframe. The commenters noted some exceptions to the 5-day timeframe, and that in the early years of HH PPS, CMS used Q&As and letters to express its intention to refrain from penalizing HHAs that failed to submit OASIS during the 5-day timeframe under certain circumstances. In these cases, the commenters wrote that CMS allowed HHAs to either conduct a comprehensive assessment as soon as possible in the 60 day episode, or to determine appropriate OASIS responses required for payment from the clinical record when Medicare is the payer. Also, when payment-only items are collected, HHAs are not to submit these data to CMS. The commenters recommended that we amend any enforcement to consider that 100 percent compliance with the 5-day timeframe is not always achievable.

A different commenter was opposed to the proposal to require OASIS reporting as a condition for payment, noting the exceptions to the 5-day timeframe because of issues outside of the provider's control. This commenter wrote that we should not include timeframes in any submission requirement related to payment and also asked that we change enforcement to recognize that 100 percent compliance with the 5-day timeframe is not always achievable.

Several commenters were concerned about the potential for reinstitution of collection of all OASIS items for one-visit-only cases; currently HHAs limit the OASIS collection to payment-only items for one-visit patients.

One commenter wrote that the current OASIS requirements are included only in the home health CoPs, and is concerned that the proposal would lead to the use of OASIS requirements by Regional Home Health Intermediaries (RHHIs), Payment Safeguard Contractors (PSCs), and Recovery Audit Contractors (RACs) to deny or adjust claims payment. The commenter wrote that HHAs are already inundated with State and Federal audits, and that this proposal would only exacerbate the problem. Another asked us to provide additional information in the implications and consequences of policy statements regarding OASIS being a condition of payment, and asked what actions would result if an agency failed to meet the requirement.

Response: We thank the writers for their comments. We assure commenters that we have no intention that this proposed requirement would have an effect on long-standing direction associated with submitting RAPS, OASIS completion timeframes, and

instructions associated with one-visit episodes. Rather, we intend that in finalizing this policy, providers will ensure that prior to submitting a final HH PPS episode claim, a provider will have submitted an OASIS, and the HIPPS code on the final HH PPS episode claim will be consistent with the HIPPS on the OASIS validation report.

As such, we are implementing the provision to require the submission of OASIS, for final claims, as a condition of payment, and revising § 484.210 ''Data used for the calculation of the national prospective 60-day episode payment'' to reflect this requirement.

E. Qualifications for Coverage as They Relate to Skilled Services Requirements

In the proposed rule, for CY 2010, we proposed to clarify what constitutes skilled services in the home health setting with the following revisions to § 409.42. We proposed to add a qualifying instruction to § 409.42(c)(1) to explain that intermittent skilled nursing services meeting the criteria for skilled services and the need for skilled services found in § 409.32 (with examples in § 409.33 (a) and (b)) are subject to certain limitations in the home health setting.

Proposed New Paragraph § 409.42(c)(1)(i)

We proposed to describe the limitations in two new paragraphs, § 409.42(c)(1)(i) and § 409.42(c)(1)(ii). In § 409.42(c)(1)(i) we proposed that in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service only when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose.

Further, in § 409.42(c)(1)(i) we also proposed to clarify that to be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the nonskilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service.

Additionally, we proposed to further clarify in § 409.42(c)(1)(i) that in some cases, the condition of the patient may require that a service that would normally be considered unskilled be classified as a skilled nursing service given a patient's unique circumstances. This would occur when the patient's underlying condition or complication required that only a registered nurse could ensure that essential non-skilled care was achieving its purpose. However, any individual service would not be deemed a skilled nursing service merely because it was performed by or under the supervision of a licensed nurse. Where a service could be safely and effectively performed (or self administered) by the average non-medical person without the direct supervision of a nurse, the service could not be regarded as a skilled service, although a nurse may have actually provided the service.

Proposed New Paragraph § 409.42(c)(1)(ii)

Additionally, we also proposed a new § 409.42(c)(1)(ii), which would clarify when patient education services as described in § 409.33(a)(3) constituted skilled services in the home health setting. Currently § 409.32(a)(3) states that patient education services are skilled services if the use of technical or professional personnel is necessary to teach patient self-maintenance. However, to address the concerns and lack of clarity surrounding when educational services are skilled services as described above, we proposed to add a new paragraph, § 409.42(c)(1)(ii). In the home health setting, skilled education services would be deemed to no longer be needed when it became apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

Proposed Change to § 409.44(b)

We proposed to revise the introductory material at § 409.44(b)(1), to refer to the newly proposed limitations of skilled services in the home health benefit at § 409.42(c)(1)(i) and 409.42(c)(1)(ii). The clauses under the revised paragraphs (i) through (iv) would remain unchanged.

Proposed Revision to § 424.22(a)(1)(i) and § 424.22(b)(2)

We also proposed to revise § 424.22(a)(1)(i) and § 424.22(b)(2) to require a written narrative of clinical justification on the physician certification and recertification for the targeted condition where the patient's overall condition supported a finding that recovery and safety could be ensured only if the care was planned, managed, and evaluated by a registered nurse. To clarify for home health agencies what specific circumstances would necessitate the involvement of a registered nurse in the development, management, and evaluation of a patient's care plan when only unskilled services were being provided, we proposed additions to the home health certification content requirements as described at § 424.22(a)(i) and recertification content requirements at § 424.22(b)(2). Specifically, when a patient's underlying condition or complication required exclusively that a registered nurse ensure that essential non-skilled care is achieving its purpose, and necessitated that a registered nurse be involved in the development, management, and evaluation of a patient's care plan, we proposed to require the physician include a written narrative on the certification and recertification describing the physician's clinical justification of this need.

Comment: Many commenters appreciated CMS' clarification of skilled services. However, many opposed CMS' proposal that a physician include a clinical justification on the certification of need for Medicare's home health services, in the scenario where a patient's need for skilled services is met solely because skilled oversight of unskilled services is required. Commenters urged CMS to reconsider this requirement, stating that such a requirement would be too burdensome for physicians to include on the certification, would be too burdensome for agencies to administer, and would result in fewer patients being referred to home health. Some commenters stated that the need for skilled oversight of unskilled services is a determination that the home health nurse makes at the initial eligibility assessment, and that this need is better understood by the nurse than it would be by the certifying physician. Further, commenters stated that this requirement would muddy issues of nursing practice by requiring more physician orders for established areas of nursing practice. Other commenters expanded on this concern, stating that by requiring the physician to

clinically justify the need for skilled oversight of unskilled services, CMS was diminishing the role and responsibility of the home health nurse to makes such an assessment. Some commenters recommended that CMS instead provide education to providers regarding when evaluation and management of unskilled services is appropriate. Another commenter suggested that we develop a national coverage determination (NCD) to address our concerns. Commenters described the challenges that home health agencies currently face in getting the physician to sign orders and plans of care, fearing that this additional physician documentation requirement could result in physicians not certifying patients for Medicare's home health benefit, ultimately resulting in access to care issues for patients. Other commenters stated that this requirement would have no positive effect; because so few patients meet the skilled requirement based solely on this need, the narrative requirement would not enhance program integrity efforts. Commenters contended that the requirement would increase HHA costs, since HHAs would need to track the physician's compliance. One commenter suggested that we instead provide the patient's certifying physician with a list of services provided to the patient to achieve more physician involvement with the home health patient. Another commenter suggested instead of requiring a physician narrative in this scenario, we instead require that the plan of care contain a clinical justification for the skilled oversight. Other commenters stated that a narrative requirement is not the way to achieve more physician involvement and another commenter stated that a narrative requirement would take away from the time a physician spends with the patient. Instead, CMS should look to new OASIS–C process measures which would require the home health agency to contact the physician more frequently. Another commenter suggested that we instead require a clear order from the physician for management and evaluation of the plan of care. Another commenter stated that this narrative requirement more appropriately belongs in the physician fee schedule rule, while another commenter stated that should CMS finalize this requirement, we place the burden of compliance on the physician. Finally, a commenter stated this requirement is especially problematic for dual eligible home health patients. The commenter asserted that Medicaid does not have a comparable narrative requirement. Therefore, should an agency believe that the payer source for a patient is Medicaid, it would not obtain the narrative from the physician. If later the agency determines that Medicare should be the payer for the services rendered to such a patient, the agency would not be able to satisfy this narrative requirement.

Response: We thank the writers for their comments. However, we continue to believe that requiring a physician to complete a clinical justification on the certification in this targeted scenario addresses a specific program vulnerability which has been identified by our Medicare contractors, and is a first step in addressing vulnerabilities identified by the Office of Inspector General (OIG). We also believe that this requirement will result in a minimal burden on the physician, and minimal costs to the HHA, given that this requirement applies only to the small percentage of patients who require only skilled oversight of unskilled care. The brief narrative should be a simple task for the physician because of the physician's responsibility for the clinical determination of the patient's skilled need as part of the certification or recertification requirement.

We remind commenters that a physician must certify that home health services are required because the individual patient needs skilled nursing care on an intermittent basis, or physical or speech therapy, or continued occupational therapy in order for a patient to be eligible for the benefit. We are concerned that many commenters state that a physician's involvement in this scenario is negligible; that the physician relies solely on the home health nurse's determination when certifying the need for the Medicare home health benefit. We remind commenters that the physician has always been responsible for certifying that the unique condition of the patient warrants eligibility for Medicare's home health benefit. A home health agency's recommendation alone is not sufficient for a physician to certify the need for the benefit. While our regulations have always required the physician to review the individual patient's needs and unique clinical condition as part of the certification and recertification requirement, we believe the commenters are often correct that the physician may rely too heavily on the home health staff for the determination of skilled need for Medicare's home health benefit.

We also would like to assure nurses that this requirement is not an attempt by CMS to diminish in any way the essential and important role that skilled nurses play in the assessment of a home health patient's needs. While the home health nurse is responsible for initiating, managing and evaluating the resources needed to promote the Medicare home health patient's optimal level of well-being, this does not diminish the responsibility of the physician to ensure that the unique condition of the patient warrants the need for Medicare's home health benefit. The physician is currently responsible to carefully synthesize data regarding the patient's condition and assess whether this patient's unique condition requires Medicare's home health services. The physician is accountable for the accuracy of the certification of need for home health services. We agree with the commenter that providing the physician with a list of patients' home health services provided may be useful. Similarly, we agree with the commenter that inclusion of a clinical justification on the plan of care is a good idea, and that a clear physician order for this service should be present. We also agree that the OASIS process measures will more actively involve the physician in some aspects of patient care. Additional provider education associated with management and evaluation is something that CMS will consider providing. However, we do not believe that an NCD is appropriate in this scenario because skilled services are covered under the home health benefit, and appropriate use of management and evaluation management of the plan of care is a skilled service. Regardless, none of these suggestions would replace the physician's accountability associated with the certification and recertification of need for Medicare's home health benefit, nor would these suggestions address the program vulnerability associated with this specific category of home health patient. And, because the physician's certification and recertification of the need for Medicare's home health benefit is fundamental to eligibility, we disagree with the commenter that this provision would be more appropriately addressed in the physician fee schedule rule. Regarding the commenter's suggestion that we hold the physician accountable for complying with this requirement, we continue to believe that each agency is responsible for ensuring that the certification and recertification requirements are met, but we also reiterate the physician's accountability associated with the certification and recertification, as they are part of the medical record.

Therefore, we are finalizing the following policy: When a patient's underlying condition or complication requires that a registered nurse ensures that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management and evaluation of a patient's care plan, we will require that the physician include a written narrative on the certification and recertification describing the physician's clinical justification of this need.

Comment: Some commenters encouraged CMS to allow the narrative to be submitted as an attachment. These commenters believe that home health agencies and physicians which have electronic medical records should not be forced to include the narrative on the certification and recertification forms. Some commenters stated that CMS should provide examples to help home health agencies and physicians understand the scope of acceptable responses. Another commenter stated that the requirement would be meaningless since there are no specific guidelines for the content of the statement, and there would be no way to determine that the narrative is completed. Similarly, a commenter stated that if physicians were required to include a clinical justification narrative on the certification, the narrative would be simply a restatement of the nurse's justification, or it would be a prefabricated statement.

Response: Our intent is for the physician to justify his or her certification of skilled need in the scenario where only unskilled services are being provided. We understand that many physicians would prefer to dictate rather than hand-write their clinical findings, and we agree with commenters who stated that we should take into account that some providers have electronic health record systems and may more easily produce an addendum containing the clinical justification. Therefore, we have decided that a typed addendum containing the narrative which is electronically or hand signed by the physician would be acceptable. We also appreciate the commenter's concern that a home health nurse may compose the narrative for the physician and that we should clarify the criteria associated with the narrative requirement. We expect that the narrative must be composed by the physician performing the certification or recertification and not by other home health personnel. Regarding the commenter's concern associated with dual eligible patients, especially given that Medicaid is the payer of last resort, we would encourage agencies to ensure that all Medicare criteria are met if the agency believes that Medicare may be the appropriate payer for a patient.

We believe that these requirements regarding the certification and recertification are a first step in ensuring that only home-health eligible patients receive the benefit. We disagree with the commenter who suggested we include an illustrative example of narrative language, since the intent of the narrative is to capture the physician's synthesis of each patient's unique conditions.

We are modifying our original proposal in that we will allow the narrative to either be part of the certification and recertification forms, or to be an addendum to the certification and recertification forms which is electronically or hand signed by the physician. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum. The narrative must reflect the patient's individual clinical circumstances.

Comment: A commenter stated that CMS should issue specific Medicare coverage guidelines that clearly differentiate non-covered custodial or medically unnecessary care under Medicare home health from covered rehabilitative, acute or curative care.

Response: We thank the commenter for the suggestion. We believe that the commenter is asking CMS to expand our skilled services clarification to better clarify CMS' definition of custodial care. We believe that this is outside of the scope of that which we solicited comments, which was to clarify CMS' regulations concerning skilled services in the home health setting. However, we will briefly address this as it is a related topic. Custodial care is not considered skilled care. We suggest the commenter refer to regulations at 42 CFR 409.45(b) and 42 CFR 409.49(d) for some clarification regarding custodial care in the home health setting. We suggest the commenter refer to regulations at 42 CFR 409.49(d) where we specifically stipulate the exclusion of housekeeping services from home health services, and also stipulate that services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage. We also note that personal care and some incidental services can be provided in the course of a covered Medicare home health visit. 42 CFR 409.45(b) defines what constitutes a home health aide visit. This section explains that the reason for the aide visit must be to provide hands-on personal care to the beneficiary or services that are needed to facilitate treatment of the beneficiary's illness or injury. Please note 42 CFR 409.45(b)(1)(i) provides examples of covered personal care and 42 CFR 409.45(b)(4) permits an aide to perform services incidental to a covered visit. These incidental services may include changing bed linens, personal laundry, or preparing a light meal. Therefore, a home health aide may perform some incidental services which do not meet the definition of a home health aide service (light cleaning, preparation of a meal, taking out the trash, shopping, etc.). However, the purpose of a home health aide visit may not be to provide these incidental services since they are not health-related services, but rather are necessary household tasks that must be performed by anyone to maintain a home. It is important to note that to be considered a covered Medicare home health visit, the purpose of the home health visit cannot be to provide the ''incidental or custodial'' services.

Comment: A few commenters supported the proposed narrative requirement. One commenter recommended that we require the narrative for ALL home health episodes, regardless of services ordered, stating that this would be encourage more physician involvement with the home health patient.

Response: The commenter has correctly interpreted our interest in enhancing physician accountability and involvement with the home health patient. However, at this time we are proposing to require the narrative for only one targeted nursing service. Program vulnerability has been identified in this scenario, because the patient is receiving only unskilled services, which would normally not result in eligibility to Medicare's home health benefit. Therefore, we believe it is prudent to require the physician to provide this clinical justification of why a patient's condition would require skilled nursing management and evaluation (M&E) of the patient's care plan.

Comment: A commenter recommended that CMS reconsider the restrictive interpretation of skilled oversight of the plan of care (POC). Providers are often compelled to

discharge patients from Medicare based on a very limited interpretation of skilled oversight when it is apparent that the patient is in advanced stages of chronic illness and will likely relapse once nursing oversight is discontinued. Such patients may become stable for several weeks and under the policy above would be considered non-covered and discharged from Medicare home health. Patient outcomes could be improved if such patients were offered continuing care coordination during periods of stability. The commenter suggested we modify coverage guidelines to allow home healthcare to continue for observation and monitoring of a plan of care through periods of relative stability if the patient is in advanced stages of chronic illness and likely to deteriorate without skilled care.

Response: We thank the writer for this perspective. However, we are not excluding beneficiaries in advanced stages of chronic illness from qualifying for this service. When a chronically ill patient with an underlying condition or complication requires skilled nursing personnel to manage the plan of care then this service is indeed indicated until the treatment regimen has essentially stabilized. If the combination of the patient's underlying condition, age and immobility creates a high potential for serious complications which require that only a registered nurse can ensure that essential non-skilled care is achieving its purpose then the patient is indeed eligible for this service. However when the patient's treatment regimen is essentially stabilized and skilled nursing visits are not necessary to manage and supervise the home health aide the patient will not require this type of care and does not meet the definition of needing a skilled service for purposes of Medicare home health eligibility, per sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act.

Comment: A commenter urged CMS to undertake a similar initiative to set out coverage conditions for therapy services in the home health regulations.

Response: In response to a commenter's request for CMS to provide clarification of coverage of therapy services we are referring the commenter to the following existing section of the Code of Federal Regulation, 42 CFR 409.44(c). We believe that this section adequately sets out the circumstances under which therapy services are covered. However, we thank the commenter for this opportunity to remind HHAs of their ongoing responsibility to evaluate the patient's need for therapy and provide all covered home health services (except durable medical equipment) either directly or under arrangement while a patient is under a home health plan of care.

Comment: A commenter stated that the revisions proposed by CMS will make it more difficult for Medicare patients to obtain skilled nursing management and evaluation of the care plan. The commenter also stated that the requirement places an unrealistic expectation on a patient or caregiver to gauge effectively whether non-skilled care is achieving its purpose, that CMS wrongly hinges coverage on the complexity of unskilled services, and provides no clear guidance for how to determine complexity. The commenter further states that the proposed clarifications add confusion to the current standard.

Response: We disagree with the commenter's statement that the revisions to the skilled nursing management and evaluation of the care plan will make it more difficult for Medicare patients to obtain this skilled service. We also point out that we would expect the home health agency rather than the patient or caregiver to gauge the effectiveness of the services being provided. As we stated earlier, the proposed regulation changes reflect long-standing manual guidance. We also believe that the commenter's concern about no clear guidance to assess the complexity of the unskilled services further reveals the need for the certifying physician to clearly describe what unique aspect about the patient's condition would require skilled management and evaluation of these unskilled services. However, we understand the commenter's concern. The proposed regulation text stated, ''* * * in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service *only* when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose.'' (Emphasis added.)

For better consistency with long standing manual guidance, we will remove the word ''only'' after ''reasonable and necessary skilled services * * *''. The modified regulation text is more consistent with long standing manual guidance. The finalized regulation text reads, ''* * * in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose.''

Comment: One commenter stated that additional physician visits, phone calls, or paying more for oversight is unlikely to produce meaningful genuine physician involvement. These proposals do not address the fundamental problem of too little physician time to fully support the patient at home. Additional requirements are likely to produce paper or rote compliance at best and at worst will discourage some physicians from referring appropriate patients to homecare. Another commenter stated that the best approach to involving physicians in homecare rests in new models of chronic care management that integrate primary care practice that are committed to home-based care with HHAs into a single, consolidated chronic care service.

Response: We are grateful for the comments. We will consider the suggestions regarding innovative approaches to increasing physician involvement in the plan of care in future rulemaking. However, we again remind commenters that by signing the certification and recertification, the physician is accountable for attesting that the beneficiary is in need of Medicare's home health services, and that the certification and recertification are part of the patient's medical record. And, Medicare reimburses physicians for their work associated with the certification, recertification and plan of care oversight.

Comment: Some commenters expressed concerns with CMS' clarification which described that skilled education services would be deemed to be no longer needed when it became apparent, after a reasonable period of time, that the patient, family member or caregiver could not or would not be trained. Some commenters asked that CMS better clarify timeframes that would be appropriate for these skilled training services. Other commenters stated that unless CMS defines what is a ''reasonable period of time'', the clarification isn't helpful. Other commenters stated that when a patient or caregiver appears incapable of learning, more training would be justified. Another commenter suggested that instead of clarifying this in regulation, we should increase the educational and outreach efforts of our contractors.

Response: This regulation clarification codifies long-standing guidance which has been present in Medicare's Benefit Policy Manual. We believe it inappropriate to assign specific timeframes for patient education services because the length of

time a patient or family or caregiver needs should be determined by assessing each patient's individual condition and other pertinent factors such as the skill required to teach the activity and the unique abilities of the patient. It is important to know that teaching activities must be related to the patient's functional loss, illness, or injury. However, we disagree with the commenter who suggested that when a patient or caregiver is incapable of learning that more education is needed. Medicare's home health benefit is not intended to provide training and education to patients, families, caregivers for an infinite period of time.

To summarize, we are finalizing a number of provisions as they relate to skilled services in the home health setting. Specifically, we are clarifying what constitutes skilled services in the home health setting with the following revisions to § 409.42. We are adding a qualifying instruction to § 409.42(c)(1) to explain that intermittent skilled nursing services meeting the criteria for skilled services and the need for skilled services found in § 409.32 (with examples in § 409.33 (a) and (b)) are subject to certain limitations in the home health setting.

We are revising the introductory material at § 409.44(b)(1), to refer to the new limitations of skilled services in the home health benefit at § 409.42(c)(1)(i) and § 409.42(c)(1)(ii). The clauses under the revised paragraphs (i) through (iv) will remain unchanged.

We are also revising § 424.22(a)(1)(i) and § 424.22(b)(2) to require a written narrative of clinical justification on the physician certification and recertification for the targeted condition where the patient's overall condition supports a finding that recovery and safety could be ensured only if the care was planned, managed, and evaluated by a registered nurse. To clarify for home health agencies what specific circumstances would necessitate the involvement of a registered nurse in the development, management, and evaluation of a patient's care plan when only unskilled services are being provided, we are finalizing additions to the home health certification content requirements as described at § 424.22(a)(i) and recertification content requirements at § 424.22(b)(2).

F. OASIS for Significant Change in Condition: No Longer Associated With Payment

In the CY 2010 proposed rule we proposed to remove an obsolete reference to ''new case-mix assignments'' as a result of significant changes in a patient's condition that appeared in 42 CFR part 484 subpart E at § 484.55(d)(1)(ii). The significant change in condition (SCIC), as it relates to new case-mix assignments affecting payment, was an element of the HH PPS at the time of its first implementation in fiscal year 2000. However, as part of the HH PPS payment refinements implemented in CY 2008, we eliminated the SCIC policy, and the assignment of subsequent case-mix assignments under the HH PPS. However, it should be noted that it was not the SCIC payment policy that required the HHA to perform the assessment, but rather the significant change in the patient's condition. In the proposed rule we did not propose to change that requirement. A HHA would still be required to perform an assessment in the event that a patient experienced a significant change in condition. The proposed modification is only that a new case-mix assignment is no longer associated with this assessment.

In addition, we proposed to revise § 484.250 to delete an obsolete reference to § 484.237. Section 484.237 referred to the SCIC payment policy and was removed in the CY 2008 HH PPS final rule (72 FR 49879).

Comment: A commenter wrote that since there is no additional payment for SCICs, there is no incentive for HHAs to do additional, time-consuming, and costly OASIS assessments. This commenter stated she disagreed with this requirement, and suggested that if we wanted this additional assessment, we should increase reimbursement for it.

Response: We believe the commenter has misunderstood the text of the proposed rule. As noted in the proposed rule, we eliminated the SCIC payment policy and the assignment of subsequent case-mix assignments under the HH PPS in our 2007 (CY 2008) final rule. However it was not the SCIC payment policy that required the HHA to perform the assessment, but rather the significant change in the patient's condition. We did not propose any changes this requirement. The proposed modification was only that a new case-mix assignment is no longer associated with this assessment. Therefore there was no proposal for any additional assessments beyond those that have been requirements for some time now.

We are finalizing the provision to remove an obsolete reference to ''new case-mix assignments'' as a result of significant changes in a patient's condition that appeared in 42 CFR part 484 subpart E at § 484.55(d)(1)(ii). We are also finalizing the provision to revise § 484.250 to delete an obsolete reference to § 484.237.

G. Payment Safeguards for Home Health Agencies

In the Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2010, we also proposed several payment safeguard provisions designed to: (1) Improve our ability to verify that home health agencies (HHAs) meet minimum enrollment criteria; (2) ensure that HHAs that are changing ownership meet and continue to meet the Conditions of Participation for HHAs found in 42 CFR part 484; and (3) improve the quality of care that Medicare beneficiaries receive from HHAs.

1. Program Integrity Concerns Involving HHAs

We stated in the proposed rule that the fraudulent business practices of certain HHAs continue to cost the Medicare program millions of dollars nationwide. This issue was discussed in a recent report issued by the Government Accountability Office (GAO) entitled ''Improvements Needed to Address Improper Payments in Home Health'' (GAO–09–185). This report stated that, nationwide, ''spending on the Medicare home health benefit grew about 44 percent from 2002 through 2006, despite an increase of just less than 17 percent in the number of beneficiaries using the benefit during that 5-year period.'' It also stated discrepancies in a number of States between the number of HHAs that billed Medicare and the increase in the number of Part A beneficiaries. For instance, between 2002 and 2006, the number of HHAs that billed Medicare rose in Florida by 100 percent, in Michigan by 62 percent, in Illinois by 59 percent, in Ohio by 42 percent, in Arizona by 32 percent, and in the District of Columbia by 67 percent. However, the GAO reported, the increases in the number of Part A beneficiaries who used HHA services in these six jurisdictions were as follows: Florida—28 percent; Michigan—19 percent; Illinois—23 percent; Ohio—14 percent; Arizona—4 percent; and the District of Columbia—2 percent.

The disparity in many jurisdictions between the increase in the number of HHAs and the rise in the number of beneficiaries is so overwhelming that it cannot be attributed solely to an aging populace. The fact that, as shown above, between 2002 and 2006, the number of HHAs in Arizona rose at a rate 8 times greater than the number of Part A beneficiaries that use HHA services and that the rate was *an astounding* 33 times greater in Washington, DC must raise

serious questions as to the legitimacy of some of these entities.

As explained in the preamble to the proposed rule, the GAO report also outlined a number of instances of allegedly fraudulent activities on the part of HHAs. In a particularly glaring example in Houston, Texas, the GAO noted the following: ''One PSC (Program Safeguard Contractor) interviewed 670 Houston beneficiaries who had the most severe clinical rating and who were patients of HHAs identified by the PSC as having aberrant billing patterns. The PSC found 91 percent of claims for these beneficiaries to be in error. Nearly 50 percent of the beneficiaries were not homebound and therefore were not eligible to receive any Medicare home health services. The investigators also found that while 39 percent of the beneficiaries they interviewed were eligible for the benefit, their clinical severity had been exaggerated. The PSC concluded that only 9 percent of claims for the 670 beneficiaries were properly coded. In addition, the PSC found that other home health beneficiaries it interviewed were not homebound; for instance, some were mowing their lawns when investigators came to interview them.''

In its report, the GAO also cited a number of court cases and actions of the Office of Inspector General (OIG) that resulted in the criminal convictions of or settlements with owners of various HHAs. In one 2007 case, the owner of a Louisiana HHA was convicted of defrauding Medicare over a 5-year period and was ordered to pay more than $4.6 million in damages. In 2004, the owner of the two largest HHAs in California pled guilty to defrauding the Medicare program of approximately $40 million and filing false tax return to conceal the income. In 2008, an HHA in Florida, pursuant to an OIG settlement, agreed to pay $178,000 to settle a case in which it was alleged that the provider paid kickbacks for beneficiary referrals. In another OIG settlement, this time in 2005, a Pennsylvania HHA agreed to pay $300,000 to settle a case in which it was alleged to have paid kickbacks under Medicare.

In light of all this, the GAO concluded, in part, that ''In the absence of greater prevention, detection, and enforcement efforts, the Medicare home health benefit will continue to be a ready target for fraud and abuse.'' More specifically, it stated that ''gaps in screening potential and current HHAs may allow problem providers to enter and remain in the Medicare program.''

The problem of fraudulent activity has been especially acute in the States of Texas and California. As we stated in the proposed rule, in Los Angeles County in California, the amount of money for which HHAs in that county billed Medicare between Fiscal Years 2003 and 2006 rose from $569 million to $921 million, an increase of 62 percent, and one that was not accompanied by a similar increase in the county's Medicare beneficiary population. There has also been an abnormal proliferation of HHAs in California as a whole. Between October 2002 and May 2007, the number of HHAs in the State rose by 25 percent—again, without a concomitant upswing in the number of Medicare beneficiaries in California, all of which suggested that there may also be an increase in improper billing. Moreover, we have seen instances—notably, though not exclusively, in South Florida and Texas—in which specific HHAs have changed ownership on a frequent basis. The new owners, however, have been mere nominal figures.

We also stated in the proposed rule that the problems we identified have been seen with HHAs on a far greater scale than with any other type of certified provider. The dramatic rise in the number of HHAs in relation to the increase in Medicare beneficiaries has not been duplicated by any other certified provider types.

2. Provisions of the Proposed Regulation

We proposed the following payment safeguard provisions:

- In § 424.530(a)(8), we proposed to deny Medicare billing privileges to a prospective HHA if the HHA is determined, under proposed 42 CFR 489.19, to be sharing, leasing, or subleasing its practice location or base of operations identified in section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.
- In § 424.535(a)(11), we proposed to revoke the Medicare billing privileges of an HHA that is determined, under proposed 42 CFR 489.19, to be sharing, leasing, or subleasing its practice location or base of operations identified in section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.
- In § 424.540(b)(3), we proposed to exclude home health agencies from the existing language in § 424.540(b)(3), which states that the reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.
- In § 424.540(b)(3)(i), we proposed to require that an HHA whose Medicare billing privileges are deactivated under the provisions found at 42 CFR 424.540(a) must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.
- In § 424.550(b)(1), we proposed to require that if the owner of a home health agency sells (including asset sales or stock transfers), transfers or relinquishes ownership of the HHA within 36 months after the effective date of the HHA's enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner.
- In § 424.550(b)(1)(i), we proposed that in the situation described in proposed § 424.550(b)(1), the prospective owner of the HHA must instead enroll in the Medicare program as a new HHA under the provisions of § 424.510.
- In § 424.550(b)(1)(ii), we proposed that in the situation described in proposed § 424.550(b)(1), the prospective owner of the HHA must obtain a State survey or an accreditation from an approved accreditation organization.
- In § 489.12(a)(5), we proposed that CMS deny a provider agreement to a prospective HHA that is determined to be sharing, leasing, or subleasing its practice location or base of operations identified in section 4 of its Medicare provider enrollment application with or to another Medicare enrolled HHA or supplier in violation of the HHA space sharing prohibition set forth in proposed § 489.19.
- In § 489.19(a), we proposed that an HHA be prohibited from sharing its practice location or base of operations identified in section 4 of its Medicare provider enrollment application with another Medicare-enrolled HHA or supplier.
- In § 489.19(b), we proposed that an HHA be prohibited from leasing or subleasing its practice location or base of operations identified in section 4 of its Medicare provider enrollment application with another Medicare-enrolled HHA or supplier.

We also solicited comments on whether there were legitimate business reasons for a Medicare-enrolled HHA to share space with another Medicare-enrolled HHA or supplier when there is common ownership. Likewise, we solicited comments on whether there were legitimate business reasons for a Medicare-enrolled HHA to be co-located with another Medicare-enrolled HHA or supplier when there was no common ownership. Finally, we solicited comments on whether there were

legitimate business reasons for a Medicare-enrolled HHA to engage in leasing or subleasing arrangements with a Medicare-enrolled supplier when there was common ownership.

3. Analysis of and Responses to Public Comments

We received approximately 20 timely public comments in response to the proposed payment safeguard rule. The following is a summary of the comments received and our responses:

a. Sharing and Leasing of Space

Comment: Several commenters opposed the space-sharing provision in proposed 42 CFR 489.19(a). These commenters contend that this provision could preclude arrangements in which an HHA also provides unrelated services from a single location, for example, influenza vaccine clinics under a supplier number; outpatient therapy services under Medicare Part B; preventive nutrition services; hospice services; DME; and infusion supplies and services. One commenter stated that many health systems operate out of a single practice location in the provision of a broad array of items and services. Another commenter, too, stated that corporations often operate multiple provider and supplier types out of the same location; an HHA, for instance, might operate a DMEPOS supplier and a hospice out of the same site. Another commenter noted that arrangements in which an HHA, hospice and DMEPOS share a common location would be known to CMS via the respective providers'/suppliers' completion of the applicable CMS–855 application, which already enables CMS to monitor such arrangements closely; the commenter added that neither CMS nor the OIG has demonstrated a compelling basis to disrupt such arrangements if they are currently in compliance. Yet another commenter noted that a number of HHAs are commonly owned and operated as a result of organizational mergers and are involved in completely legitimate arrangements; the commenter did not understand why such arrangements should be disrupted.

Response: Based on these and other comments received regarding proposed § 489.19(a) and our concern that a broad-based prohibition on co-location policy may negativity impact the health care delivery for some services, we have decided not to include this provision in the final rule. However, we continue to have concerns about these arrangements and will consider our administrative remedies to address our concerns. We are especially concerned about an HHA that maintains a practice location in one State and furnishes services to Medicare beneficiaries in another State. We are also concerned about the HHAs that have merged or consolidated their operations into a single practice location, but continue to operate as distinct entities.

As indicated in the preamble, having multiple HHAs at a single site makes it extremely difficult to determine which HHA is in operation at a given time, which HHA has actual control over certain aspects of the practice location, etc. If an HHA thus does not have a valid practice location, it is considered to be non-operational and, by extension, out of compliance with the HHA conditions of participation and with 42 CFR 424.510(a)(6). If the HHA thereafter bills for services out of that non-operational site, it does so inappropriately.

Comment: Several commenters stated that the ability of HHAs to share a practice location and centralized back office operations with other HHAs—or other Medicare providers and suppliers—improves efficiency and helps to keep down the costs associated with these operations by reducing rent and enabling the sharing of, for instance, billing staff and computer systems. One commenter added that such co-located entities allocate costs separately to each provider and supplier in the same way that hospitals do for their departments. Several other commenters stated that to require these HHAs and suppliers to move to separate locations if proposed 42 CFR 489.19(a) were finalized, would be unduly burdensome and costly to them; it would, for instance, require each formerly co-located provider or supplier to have separate staffs and computer systems.

Response: Based on these and other comments received regarding proposed § 489.19(a), we have decided not to finalize this provision in the final rule.

Comment: One commenter stated that having a shared practice location for various providers and suppliers is a normal, cost-efficient method of health care delivery without any program integrity concerns. The only reason these shared practice locations have more than one provider or supplier number is that Medicare operates an enrollment system that requires separate numbers. In this same vein, another commenter stated that a centrally located organization has been forced to obtain several provider numbers in order to cover its entire service area. In other cases, the commenter, added, HHAs that deliver services across State lines (for decades, in some cases) are currently forced to obtain separate provider numbers because the States that they served have decided not to establish reciprocity agreements with bordering States.

Response: As stated above, based on these and other comments received regarding proposed § 489.19(a), we have decided not to finalize this provision in the final rule.

Comment: Several commenters stated that, under proposed 42 CFR § 489.19(a), a hospital-based HHA would not be able to share space with a DMEPOS supplier that is also owned and operated by the hospital. The commenter suggests that such arrangements pose little risk to the Medicare program.

Response: As stated above, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: One commenter urged CMS to identify more effective ways to identify the few fraudulent providers and suppliers that apply for multiple Medicare numbers for the same location. The commenter believed that CMS should establish a vetting process rather than the blanket denial of co-locations. By the same token, this vetting process must do more than allow use of the same address with separate suite numbers, as that would not be a sufficient deterrent to fraudulent providers.

Response: As stated above, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: Several commenters urged CMS to refine its proposed 42 CFR 489.19(a) to allow HHAs to share a practice location with other licensed and certified entities to use a shared practice location as long as the co-location arrangement is not used or has not been used for fraudulent or abusive purposes.

Response: As stated above, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: One commenter urged CMS to eliminate its proposal in 42 CFR 424.535(a)(11) to allow contractors to revoke the Medicare billing privileges of an HHA on the grounds that it shares a practice location with another entity that is a Medicare-certified HHA. The commenter also stated that due process procedures should be used in instances where an existing HHA is discovered to share a practice location with another HHA or supplier, and that it would be unreasonable to revoke the HHA's billing privileges on that ground if there is no concern about fraud or abuse by the organization.

Response: As stated above, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: Several commenters stated that HHAs should be able to share practice locations with other HHAs and suppliers if there is common ownership involved.

Response: As previously stated, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: Several commenters requested that CMS clarify the specific situations in which an HHA may be co-located with another entity. Another commenter stated that the space-sharing prohibition smacked of too much government interference into how HHAs do business and would do nothing for patient care.

Response: As stated above, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: One commenter disagreed with our prohibition on leasing arrangements in proposed § 489.19(b). The commenter contended that there are a variety of services that one agency may not be equipped to handle and must rely on relationships with other vendors to meet the full needs of their patients. The proposed prohibition could, therefore, hinder beneficiary access to required services.

Response: Based on these and other comments received regarding proposed § 489.19(b), we have decided not to finalize this provision in the final rule.

Comment: One commenter agreed with our proposal to prohibit an HHA from sharing space with another HHA, stating that this practice raises questions as to the viability and legitimacy of the HHA and could confuse surveyors by rendering it difficult for them to identifying which HHA they are actually evaluating.

Response: While we appreciate the commenter's support, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: Another commenter supported proposed 42 CFR 489.19(a), but sought clarification that it would not prohibit an HHA from sharing space with other types of home health related organizations such as a long-term home health program, a managed long-term care program, and a licensed certified home health services agency.

Response: While we appreciate the commenter's support, we have decided not to finalize proposed § 489.19(a) in the final rule.

Comment: One commenter supported our proposal to prevent HHAs from sharing practice locations and operations to the extent that there is no common ownership involved. This commenter went on to say that the practice of co-location makes it difficult for State surveyors and accreditors to clearly identify which agency is under review.

Response: While we appreciate the commenter's support, we have decided not to finalize proposed § 489.19(a) in the final rule.

b. Change of Ownership Provisions

Comment: Several commenters agreed with our proposal to prohibit the conveyance of a provider agreement to the new owner of an HHA if the change of ownership takes place within 36 months of the HHA's enrollment in Medicare. One commenter noted that the proposal would: (1) Eliminate situations in which HHAs are established for the purpose of being sold to persons or entities that will ultimately be the operator, and (2) ensure that persons who will operating HHAs have an understanding of the business requirements before receiving a provider agreement.

Response: We appreciate the support of these commenters.

Comment: One commenter supported our proposed change of ownership provision, acknowledging our concerns about turn-key sales of new HHAs where there is no assurance that the buyer can maintain compliance with the conditions of participation.

Response: We agree with this commenter.

Comment: One commenter suggested that CMS allow transactions involving sales and transfers of ownership of HHAs currently enrolled in Medicare for less than 3 years that are in process as of January 1, 2010 to proceed.

Response: We disagree and believe that an HHA change of ownership application that is pending as of January 1, 2010 should be subject to the provisions of this final rule.

Comment: Another commenter requested CMS to establish a ''hardship'' exemption so that legitimate HHA sales can be reviewed and permitted to proceed. The commenter stated that some HHAs sales are facilitated for entirely legitimate and unavoidable reasons, such as when a partner in a partnership dies or leaves the business and a new entity is created. The requirements of 42 CFR 424.550(b)(1) could force such a provider to go out of business; the commenter also stated that the requirements of 42 CFR 424.550(b)(1) could lead to the total devaluation of certain HHAs, and that purchasers will be unable to bill for services provided for periods as long as a year after the sale. Another commenter stated that given the significant investment of capital needed to start and operate an HHA in the current regulatory environment, an owner—in selling its HHA for entirely legitimate reasons—should be able to recoup its investment.

Response: We do not believe that a hardship exemption should be established, nor do we believe that the three-year period should be reduced. As previously stated, the purpose of this requirement is to ensure that HHAs that are sold remain in compliance with Medicare's conditions of participation. We stress that 42 CFR 424.550(b)(1) in no way prohibits an owner from selling its HHA. It merely requires that the HHA enroll as a new provider, undergo a State survey or accreditation, and sign a new provider agreement prior to being able to bill Medicare for services once again.

Comment: Several commenters requested that CMS reduce the 3-year period to 12 months under 42 CFR 424.550(b)(1) so as not to unduly prohibit legitimate sales of HHAs. One such commenter added that agencies that undergo changes of ownership that occur within 1 year fit the CMS description of ''turn-key'' operation.

Response: We do not believe that a change in proposed 42 CFR 424.550(b)(1) is warranted. We continue to believe that a 3-year period is appropriate. We believe that this change will help to ensure that individuals establishing a HHA are doing so with a long-term view of furnishing services, rather than establishing a business for the purpose of selling it a short time later. In addition, we believe that this time-frame will allow CMS to assess whether the HHA is operating in compliance with the conditions of participation and other program requirements.

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

that the newly-purchased HHA be subject to an appropriate level of review.

c. Deactivation Provisions

Comment: Several commenters expressed concern that the deactivation provision in proposed § 424.540(b)(3) could disadvantageously affect HHAs that bill Medicare on either an infrequent basis or not at all. They stated that since Medicare deactivates a provider's Medicare billing privileges if the provider has not billed Medicare for 12 consecutive months, HHAs that only sporadically bill Medicare not only may have their billing privileges deactivated frequently, but will, under the aforementioned proposed provision, have to undergo a State survey each time it seeks to reactivate these privileges. This will, the commenter believes, impose a very significant burden on such providers. One commenter also: (1) Expressed concern that a deactivation of its Medicare billing privileges would affect its ability to bill Medicaid, and (2) asked whether, if it owned an HHA and a hospice and both were enrolled in Medicare, a deactivation of its HHA billing privileges would affect its ability to continue billing for hospice services. Another commenter urged CMS to consult with State Medicaid programs prior to implementing this proposed provision. Yet another commenter stated that it was their understanding that the requirement to obtain an initial State survey under proposed § 424.540(b)(3) would be commensurate to decertification. With long timelines for obtaining surveys and with Medicare having categorized HHA surveys as Tier-4 priority, this would put HHAs out of business and, in turn, impact Medicaid-only businesses that require Medicare certification—with the end result, the commenter stated, of harming Medicaid patients. Similar concerns were expressed by a commenter regarding HHAs that only bill Medicare Advantage plans.

Response: We recognize that proposed § 424.540(b)(3) could delay an HHA's ability to reactivate its Medicare billing privileges, especially if the HHA bills only sporadically and is thus susceptible to frequent deactivations. However, we believe that this is outweighed by the strong need to verify that HHAs whose billing privileges were deactivated after 12 consecutive months of non-billing remain in compliance with Medicare's conditions of participation and other regulatory provisions. We also believe that this approach will help ensure that Medicare beneficiaries receive services from qualified HHA providers.

CMS does not currently conduct a State survey when a provider seeks to reactivate its Medicare billing privileges. As is the case with ownership changes, CMS therefore has no sure way of knowing whether the HHA, after not billing Medicare for at least a 12-month period, is still in compliance with the HHA conditions of participation; indeed, it is possible that the period of non-billing was due to the fact that the HHA was not in operation at the time. Unless CMS can determine whether the HHA is in compliance with the conditions of participation, the HHA may have its billing privileges reactivated and begin billing for services again without having been appropriately reviewed via the survey process. This could lead to inappropriate billings if HHA is indeed out of compliance with such conditions. As with 42 CFR 424.550(b)(1), we believe that 42 CFR 424.540(b)(3)(i) will help close the gap noted by the GAO in ''screening potential and current HHAs'' by ensuring that the new owners in an HHA ownership change are properly screened. With respect to the commenters' concerns related to Medicaid and Medicare Advantage billing under Medicare, the deactivation of a provider's Medicare billing privileges does not mean that the provider is no longer enrolled in Medicare. In fact, the Medicare provider agreement remains in effect. Accordingly, a deactivated HHA is still certified as a Medicare HHA. Deactivation simply means that the provider, prior to having its Medicare billing privileges reactivated, must: (1) Submit the information requested in § 424.540(b)(1) and (2) undergo a State survey or obtain accreditation to ensure that it remains in compliance with the applicable conditions of participation. Indeed, as previously indicated, there have been instances where HHAs are sold to nominal owners when the real operators are individuals who were later found to be engaging in fraudulent activity. Our current inability to conduct a State survey for most changes of ownership hinders CMS's ability to fully vet and review the HHA, its new owners, and the new operations, and makes it more likely that such sham operations can continue to exist.

With respect to situations in which a provider owns an HHA and a hospice and the billing privileges of the HHA are deactivated for 12 consecutive months of non-billing, this does not affect the billing privileges of the hospice; the hospice's billing privileges remain intact, as the HHA and the hospice are separate providers, are separately enrolled, and have separate provider agreements.

Finally, we do intend to notify State Medicaid agencies about the implementation of this provision.

Comment: Another commenter stated that proposed § 424.540(b)(3) would require those HHAs that primarily or even exclusively bill Medicaid but who are required to be enrolled in Medicare as a prerequisite thereto to submit at least one Medicare claim per year or see their Medicare billing privileges rescinded.

Response: As we previously stated, the deactivation of a provider's Medicare billing privileges is not the same as the revocation of these privileges. A deactivated provider remains enrolled in Medicare, whereas a revoked provider loses its Medicare billing privileges and is no longer enrolled in the program.

Comment: Several commenters suggested that for providers enrolled in Medicare and Medicaid, CMS not deactivate a provider's Medicare billing privileges for non-billing if the provider has submitted a bill for or been paid by Medicaid within that same 12-month period.

Response: The regulatory provisions in 42 CFR 424.540 regarding 12 consecutive months of Medicare non-billing do not allow for the level of Medicaid billings to be a consideration in the deactivation of a provider's Medicare billing privileges. This is because Medicare and Medicaid are two completely separate health programs. If we expanded 42 CFR 424.540 to allow a provider's billing history with other health plans to be a factor in determining whether to deactivate a provider's Medicare billing privileges, a situation could arise where a provider has not submitted a bill to Medicare for a 10-year period but has not been deactivated because the HHA has billed another program each year within that span. This would, in our view, defeat the purpose of 42 CFR 424.540. Besides, and as already stated, the deactivation of Medicare billing privileges does not mean that Medicare billing privileges have been revoked.

Comment: One commenter noted that the revised 42 CFR 424.540(b)(3) appears to require a new certification, but the unaltered 42 CFR 424.540(c) regarding the effective (date) of deactivation still provides that deactivation does not have any effect on a provider's participation agreement. The commenter suggested that we consider revising paragraph (c) to correlate with the changes to paragraph (b). Another commenter understood the

changes § 424.540 to mean that we now equate the requirement to obtain an initial State survey with decertification. In light of the extremely long timelines for obtaining initial surveys from States and accrediting organizations, the commenter stated such a requirement would put many legitimate home health agencies that are part of the 2,000 agencies that CMS estimates will be deactivated out of business.

Response: We agree that there is a discrepancy. We have therefore not included our proposed revision to § 424.540(b)(3) in the final rule. We believe that this change will eliminate the perception that deactivation and decertification are one in the same.

Comment: One commenter expressed support for our proposed changes regarding space sharing, ownership changes, and deactivations, stating that the instances of fraud and abuse reported by CMS justify changes. The commenter suggested, however, that CMS consult with the HHS Office of Inspector General, the Government Accounting Office, and the U.S. Department of Justice for alternative perspectives on the appropriate length of billing inactivity that warrants a State survey or accreditation prior to reactivation.

Response: We appreciate both the commenter's support for our proposed provisions and the suggestion regarding the consultation of other law enforcement bodies. We have, in fact, consulted with other agencies in the past regarding the 12-month deactivation policy outlined in § 424.540(a)(1). However, we believe that they would support every effort on our part to ensure that HHAs remain in compliance with Medicare's conditions of participation before their Medicare billing privileges are reactivated. We further believe that 12 consecutive months of non-billing by the provider—a lengthy period in and of itself—constitutes sufficient justification for CMS to attempt to reconfirm that the provider meets the HHA conditions of participation.

d. General Comments

Comment: One commenter believed that CMS, in its proposed program safeguard initiatives, was attempting to use a ''broad brush'' approach to combating fraud, that CMS seems to view all home health providers as fraudulent, and that the proposed initiatives will harm honest HHAs. The commenter also stated that the States with the highest levels of HHA fraud do not have significant barriers to entry, such as a State-mandated certificate of need (CON). The commenter stated that CMS should consider the correlation between CON states and the frequency of fraud and abuse. Finally, the commenter recommended, in lieu of the proposed program integrity initiatives, increased funding of survey and certification efforts and urged CMS to seek out the root cause of fraudulent behavior.

Response: We recognize that the vast majority of HHAs participating in the Medicare program are honest. However, the information cited in the preamble to the proposed rule—as well as the conclusions drawn by the Health and Human Services' Office of Inspector General—provide reason and concern for us that HHA fraud is a prevalent problem that, and in our view, warrants additional review and action to address this issue.

Comment: Several commenters expressed concern about the impact of proposed § 424.540(c) and § 424.550(b) on State survey agencies and accreditation organizations. They contended that these agencies and organizations have experienced—and, in some cases, are still experiencing—major backlogs in the number of pending HHA request for certification or accreditation. Some State agencies, another commenter stated, are not conducting new HHA surveys at all at the current time. Requiring a new survey/accreditation pursuant to each change of ownership and reactivation of Medicare billing privileges will result in even larger backlogs, which in turn will further delay the ability of HHAs to obtain a survey or accreditation in a prompt fashion. One commenter stated that it will be impossible for State survey agencies and accrediting bodies to resurvey 2,000 CHOWs that CMS reports occur annually.

Response: We understand the commenters' concern regarding workload implications for State survey agencies and deemed accrediting organizations. We believe that HHAs undergoing an ownership change or having their billing privileges reactivated must meet the conditions of participation and other program requirements in order to participate in the Medicare program.

Comment: One commenter recommended that CMS appropriately fund State agencies to handle the increased survey workload.

Response: As stated above, we understand the workload implications for State agencies and deemed accrediting organizations. Moreover, we are aware of the potential funding issues raised by the commenter.

Comment: One commenter stated that CMS must reevaluate its projections for the number of HHAs that will be impacted by the proposed CHOW requirements (2,000) and deactivation requirements (2,000). If these numbers are correct, CMS' proposals will result in requiring resurvey of 40% of the 9,500 home health agencies annually.

Response: We believe that the projections contained in the proposed rule are accurate and that the final rule is sufficiently clear as to the number of surveys that would have to be performed.

Comment: One commenter supported the proposed changes regarding space-sharing and changes of ownership, and added that CMS should begin even more active enforcement. This should include ensuring that all new enrollment applicants have a timely, thorough on-site review of clinical, operational and financial policies and processes prior to being granted enrolled status.

Response: We appreciate the commenter's support and note that we are undertaking a number of efforts to reduce fraud and abuse.

Comment: One commenter made a number of recommendations to CMS with respect to the combating of fraudulent activity in the HHA arena. These included: (1) Expanding educational efforts regarding compliance; (2) establishing a Federal requirement that administrators of home health are credentialed by a nationally recognized body; (3) establishing certification requirements for financial managers; (4) enacting a targeted moratorium on new HHAs; and (5) working with the industry to ensure that reports of fraudulent activities are acted upon promptly.

Response: We appreciate these suggestions and will take them under advisement.

Comment: One commenter suggested that CMS: (1) Enhance the Provider Enrollment, Chain and Ownership System (PECOS) to automatically identify HHAs located at the same practice location; (2) update section 12 of the CMS–855A form to include questions regarding office space, similar to the questions contained on the CMS–855B application for physical therapy and occupational therapy groups; and (3) perform site visits for some new providers.

Response: We appreciate these suggestions and will take them under advisement, though we note that CMS has increased the number of site visits it performs in certain high-risk areas for new and existing HHAs.

Comment: One commenter suggested that we describe the method by which HHAs can consolidate under one provider number without financial

consequence, and that CMS allow HHAs that intend to consolidate up to 12 months to do so.

Response: HHAs with multiple provider agreements for agencies at the same location can voluntarily terminate a provider agreement and merge the multiple HHAs into a single organization.

Comment: One commenter suggested that the intent of the States in requiring a prospective Medicaid provider to be enrolled in and certified by Medicare was to pass on the cost of the survey and certification of Medicaid-only agencies to the Federal Government and suggested that CMS resolve this with the States.

Response: We believe that this comment is outside the scope of this final rule.

Comment: One commenter asked for clarification on how HHAs are to be notified when their Medicare billing privileges are deactivated.

Response: In the event a claim is submitted after 12 consecutive months of non-billing, the claims processing system will place a message on the remittance notice stating ''This provider was not certified/eligible to be paid for this procedure/service on this date of service.'' We do not expect that this message will be implemented until CY 2010.

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

- We are not adopting § 424.530(a)(8) in this final rule.
- We are not adopting § 424.535(a)(11) in this final rule.
- We are not adopting § 489.12(a)(5) in this final rule.
- We are not adopting § 489.19(a) in this final rule.
- We are not adopting § 489.19(b) in this final rule.
- We proposed to exclude HHAs from the existing language in § 424.540(b)(3), which states that the reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement. We have decided not to include this proposed revision to § 424.540(b)(3) in the final rule. We are also making it clear that under proposed § 424.540(b)(3)(i), which is included in the final rule, an HHA undergoing a change of ownership within the first 36 months after its enrollment remains Medicare-certified and that its provider agreement has not been revoked. The deactivated HHA's certification, provider agreement, and status as an enrolled HHA remain intact. However, it must obtain a new survey or accreditation.

H. Physician Certification and Recertification of the Home Health Plan of Care

a. Background

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require that a plan for furnishing home health services be established and periodically reviewed by a physician in order for Medicare payments for those services to be made. Our regulations at § 409.43(e) specifically state that a home health POC must be reviewed, signed, and dated by the physician who reviews the POC (as specified in § 409.42(b)) in consultation with agency clinical staff at least every 60 days (or more frequently as specified in § 409.43(e)(1)). Additionally, § 424.22(b) states that a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the home health POC. These schedules, for the review of the POC and the recertification, coordinate with the 60-day episode payment unit under the HH PPS. In implementing the statutory requirement as well as these regulations, we believed that these requirements would encourage enhanced physician involvement in the HH POC and patient management, and would include more direct ''in-person'' patient encounters (as logistically feasible).

Currently, physicians are paid for both the certification and recertification of the HH POC under HCPCS codes G0180 and G0179, respectively. The basis for the payment amounts of these physician services is the relative resources in RVUs required to furnish these services. We believe physician involvement is very important in maintaining quality of care under the HH PPS.

In the HH PPS proposed rule published in the October 28, 1999 **Federal Register** (64 FR 58196), we had proposed to require the physician to certify the case-mix weight/home health resource group (HHRG) as part of the required physician certification of the POC. This reflected our belief that the physician should be more involved in the decentralized delivery of home health services. However, in the final rule published in the July 3, 2000 **Federal Register** (65 FR 41163), we did not finalize that proposal and decided to focus our attention on physician certification and education in order to better involve the physician in the delivery of home health services.

b. Solicitation of Comments

It has come to our attention that physician involvement in the certification and recertification of HH POC varies greatly. While some physicians have direct contact with their patients in the delivery of home health services, we believe that a significant number of physicians provide only a brief, albeit thorough, review of the HH POC, without any direct contact with the patient. We continue to believe that active involvement of the physician, including ''in-person'' contact with the patient, during the certification and recertification of the HH POC is essential for the delivery of high quality HH services.

In the Physician Fee Schedule proposed rule published in the July 7, 2008 **Federal Register** (73 FR 38578), we mentioned several options to enhance direct contact between the physician and the patient. First, we considered a review of the RVUs associated with the certification and recertification of the HH POC. As a result of that review, the payment amounts to physicians could be reduced based on a more accurate determination of the actual RVUs required to provide these services. We also considered proposing new requirements; for example, a requirement for ''direct'' patient contact with the physician, to ensure more active physician involvement in the certification and recertification of the HH POC. We specifically solicited comments on these policy options.

In the November 19, 2008 final rule, we expressed our appreciation for the comments and responded that we would continue to analyze and consider the comments and suggestions in future rulemaking. Additionally, as a result of comments received on the above physician rule, as they relate to physician-patient contact, we are considering the possibility of requiring physicians to make phone calls to patients at various times over the course of home health treatment (prior to recertification), as a means to promote that physician-patient contact and to help ensure the delivery of high quality HH services to our beneficiaries.

In the HH PPS proposed rule for CY 2010, we specifically solicited additional comments on this topic.

Comment: While commenters agreed that increasing physician involvement in home health patient care was a positive step, they were not supportive of requiring a face-to-face encounter between patients and physicians, or of requiring telephone contact, prior to physician certification or recertification

of the plan of care. Some felt this would be burdensome to physicians and would create a significant barrier to patients seeking home health services. Several pointed out that there was no analysis to suggest that face-to-face or telephone encounters would improve outcomes, and questioned the value of such a requirement, given its cost. A few mentioned that the underlying problem was inadequate payment to physicians; some stated that without reimbursement, physicians were not likely to be cooperative; one wrote that this suggestion did not address the fundamental problem of too little physician time to support patients at home.

One commenter wrote that the level and frequency of physician contact with patients should be determined by the physician, based on the patient's medical needs. A few commenters noted that such a requirement would interfere with the professional judgment of the physician, failed to recognize that nurses and therapists provide OASIS assessment of all patients prior to physician certification, and noted that homebound, infirm or disabled patients should not be forced to leave home for a doctor's visit. They noted that leaving home may be a considerable and taxing effort for homebound patients, especially in rural areas, when there are weather issues, or where patients have no caregiver or transportation. One commenter asked what would happen if the patient refused to go.

Several commenters pointed out that existing laws already establish serious criminal and civil sanctions for physicians who knowingly and falsely certify that a patient is homebound and needs home health. Additionally, they stated that there are no reports of quality of care problems related to the absence of a face-to-face physician encounter.

While a telephone contact could be more convenient, commenters felt that it would not accomplish much other than confirm to the physician that the patient exists and possibly hear the patient express things about his or her condition or needs. They noted that it would be difficult for the home health agency to validate that a call actually occurred if the agency were not a direct party to it. Others noted that physicians would have to make such calls after hours, given their busy schedules, and this could be disruptive to homebound patients, many of whom are elderly and retire early.

A commenter mentioned that some beneficiaries don't have telephones, particularly in remote rural areas. Another wrote that patients could barely get needed prescriptions called in timely. Some commenters also wrote that requiring an encounter could be a serious claims processing issue, akin to the former M0175 component of the HHRGs. Commenters believed that the agency would not be in a position to consistently or comprehensively understand the encounters.

Commenters suggested a number of alternatives. One commenter felt the best approach to involving physicians more in home care is in new models of chronic care management that integrate primary care practices committed to home-based care with home health agencies in a single, consolidated chronic care service. This commenter is working on pilot projects with Medicare Advantage patients, and welcomes the opportunity to develop a demonstration program.

One commenter suggested we study the role of physicians in home care and determine which factors enhance the physician's ability to conduct oversight activities, ensure appropriateness of care, and work collaboratively with home health agencies without burdening beneficiaries. Another commenter recommended we consider ways to improve communication between physicians and home health agencies, particularly as it relates to follow-up when a patient's condition changes. One commenter suggested we consider the comments received upon solicitation in the Physician Fee Schedule rule, which encouraged a wider range of mechanisms to increase involvement, such as telehealth, photographic evidence, telephone, and use of advanced practice nurses (APNs) or physician assistants (PAs). Others suggested we continue the dialogue with physicians' groups and with home health agencies about this issue. Several commenters echoed the suggestion to allow APNs or PAs, within State practice guidelines, and noted that these professionals are more accessible, more open to discussion of patient issues than physicians, would reduce the burden on physicians, and improve access.

Another commenter suggested we test proposals to require encounters in demonstration projects, and establish whether the outcomes improve enough to merit the increase in costs. This commenter also suggested we consider requiring a Medicare Director, similar to those in hospice programs. In considering alternatives, another commenter wrote that physician home visits are unrealistic. This commenter noted that under current care plan oversight (CPO), physicians can count time for telephone interactions, and suggested we see if this method of oversight is widely used. He added that CMS should review practices that cannot be counted toward CPO time and consider allowing these. He also suggested that surveyors focus more on the 60-day summary to physicians.

Several commenters recommended that CMS conduct a comprehensive study on the impact and value of physician encounters as a qualifying element of Medicare home health services. These commenters suggested that in the interim, physician payment rules could be modified to limit payment for care plan recertification to those physicians who can document a face-to-face encounter with the patient prior to care plan certification.

Response: We appreciate the comments from the public on this matter and will continue to address our concerns surrounding this issue, and analyze and consider those comments and suggestions in future policymaking and future rulemaking.

I. Routine Medical Supplies

HHAs have expressed to the HHS Office of the Inspector General (OIG) some confusion regarding routine medical supplies and how we account for the cost of those supplies. Therefore, in the proposed rule we reiterated our policy regarding routine medical supplies and how they are reimbursed under the HH PPS.

Section 1895(b)(1) states that ''all services covered and paid on a reasonable cost basis under the Medicare home health benefit as of the date of the enactment of this section, including medical supplies, shall be paid for on the basis of a prospective payment amount * * *''. The cost of routine medical supplies was included in the average cost per visit amounts derived from the audit sample. These average cost per visit amounts were used to calculate the initial HH PPS rates published in the July 3, 2000 HH PPS final rule (FR 65 41184). Because reimbursement for routine medical supplies is bundled into the HH PPS 60-day episode rate and the per-visit rates, HHAs may not bill separately for routine supplies.

As noted in Chapter 7—Home Health Services of the Medicare Benefit Policy Manual (Pub. 100–02), sections 50.4.1.2 and 50.4.1.3, routine supplies are supplies that are customarily used in small quantities during the course of most home care visits. They are usually included in the staff's supplies and not designated for a specific patient. Routine supplies would not include those supplies that are specifically ordered by the physician or are essential to HHA personnel in order to effectuate the plan of care. Examples of supplies

which are usually considered routine include, but are not limited to:

A. Dressings and Skin Care

- Swabs, alcohol preps, and skin prep pads;
- Tape removal pads;
- Cotton balls;
- Adhesive and paper tape;
- Nonsterile applicators; and
- 4x4s.

B. Infection Control Protection

- Nonsterile gloves;
- Aprons;
- Masks; and
- Gowns.

C. Blood Drawing Supplies

- Specimen containers.

D. Incontinence Supplies

- Incontinence briefs and Chux covered in the normal course of a visit. For example, if a home health aide in the course of a bathing visit to a patient determines the patient requires an incontinence brief change, the incontinence brief in this example would be covered as a routine medical supply.

E. Other

- Thermometers; and
- Tongue depressors.

There are occasions when the supplies listed in the above examples would be considered non-routine and thus would be considered a billable supply, that is, if they are required in quantity, for recurring need, and are included in the plan of care. Examples include, but are not limited to, tape, and 4x4s for major dressings.

Comment: A commenter requested clarification in the final rule on some routine medical supplies that were not included in the clarification in section III.I, such as wound care supplies and colostomy supplies. Additionally, the commenter was seeks clarification of the statement, ''There are occasions when the supplies listed * * * a billable supply, that is, if they are required in quantity, for recurring need, and are included in the plan of care'' on page 40974 at the end of section III.I. The commenter asked if this represents a change from current practice.

Response: The law governing the Medicare home health prospective payment system (HH PPS) effective October 1, 2000 requires that while the patient is under a home health POC, the HHA must bill and receive payment from Medicare for all covered home health services including routine and non-routine medical supplies, except DME Medical supplies, under the consolidated billing requirements. Routine, and non-routine medical supplies, are bundled into and paid for under the HH PPS rates and are subject to home health consolidated billing, which means that Medicare will not pay separately for these items for a beneficiary who is in an open home health care episode of care. Section 50.4 of Chapter 7, ''Home Health Services'' of the Medicare Benefit Policy Manual (Pub. 100–02) defines medical supplies as ''items that due to their therapeutic or diagnostic characteristics, are essential in enabling HHA personnel to conduct home visits or to carry out effectively the care the physician has ordered for the treatment or diagnosis of the patient's illness or injury''. All supplies which would have been covered under the cost-based reimbursement system are bundled under the home health PPS. There is no limit on the number of supplies that a patient may receive from the HHA as long as the supplies are covered, reasonable and necessary and documented by the physician and kept in the patient's record by the HHA.

Miscellaneous Comments

Comment: A commenter wrote that most claims have Non-routine Supplies (NRS) level 1 or 2, and almost none have NRS level 5. This commenter wrote that there was no information in HH PPS to capture the need for expensive pleurex catheters. The commenter felt that changes in the NRS methodology may be needed to more accurately reflect supply needs.

Another commenter was concerned that certain non-routine supplies were being added to the HH PPS bundle, but were not represented in the original cost basis for PPS supply payment without appropriate payment increases. He felt this was a disincentive to adopt new technology, and fosters the use and application of older and less efficacious alternative treatments and supplies. This commenter expressed specific concern over a Pleura-evac and sophisticated but expensive wound care products, and noted that the application of these technologies cost more than the NRS allowances. He suggested we re-evaluate the classification of Pleura-evacs and establish a process to adjust the NRS allowance to accommodate the accretion of new, more expensive, NRS.

Response: We appreciate the comments on this topic, but we are not, as part of this rule, refining either the case-mix model or the NRS severity model for the HH PPS. We will consider the comments received in future rulemaking.

Comment: In the proposed rule, CMS indicated that the 60-day episode rate was based on 25.5 visits. This is incorrect because it uses LUPAs that had 4 or fewer visits that are not paid using the full 60-day episode rate. Rather 31.6 visits per episode is the correct number of visits per episode, as the initial factor used by CMS in computing the 60-day episode rate back in 2000. CMS should clarify how the 25.5 visits per episode relates to the 31.6 visits per episode that was the basis for the 60-day episode base rate.

Response: The commenter is correct that 25.5, which was the actuarial projection for FY 2001 for all episodes as spelled out in the July 3, 2000 HH PPS Final Rule, was not the proper number to use for comparison with the current non-LUPA visits per episode; we regret the error. The 31.6 was for CY 1998 (the last historical year for which data were available for the Rule), and trends at the time indicated that visits per episode were declining. While the July 3, 2000 HH PPS Final Rule did not explicitly state the projection for FY 2001 non-LUPA visits per episode, it can be gleaned mathematically from other numbers published in that final rule, and turns out to be a few visits lower than 31.6.

Comment: A few commenters wrote that LUPA rates were still less than an agency's cost of providing a visit, and asked that the rates be reviewed and increased. One commenter suggested we apply the LUPA add-on to all LUPA episodes. Another could not find support for the prediction that LUPA episodes would drop from 15 percent to 5 percent, and noted that the most recent data for his State suggested LUPA episodes were running at just over 14%.

Response: Rebasing rates is not part of this final rule. A description of the analysis supporting that the LUPA add-on apply only to first or only LUPA episodes can be found in the CY 2008 final rule (72 FR 49762). It can also be noted that an individual agency's cost of providing a visit will differ from agency to agency, however, we believe that the LUPA rates, on average, are sufficient. One should note that LUPA incidence can vary greatly from agency to agency and area to area. We intend to monitor the trend in incidence of LUPA episodes in view of the change we made to LUPA payments (the LUPA add-on) that became effective in CY 2008. It is worth noting that, nationally, the percentage of LUPA episodes continues to drop, our most recent data indicating that LUPA episodes have dropped to around 10 percent. As stated in a response to a previous comment, we believe that the appropriate time and place to deal with

any re-estimates, in these multiple areas, is if and when a rebasing for the rates were to take place.

Comment: A commenter felt that the proposed rule fell short of adopting essential reform to home health payment model and regulatory processes as suggested by MedPAC and described in the Senate Finance Committee's Chairman's Mark. The commenter believes the proposed rule can be strengthened to be consistent with health care reform goals and avoid serious consequences for Medicare, its beneficiaries, and avoid undermining access to quality home health agencies. Various commenters stated that home health is an effective approach to reducing hospital admissions and managing the long term nature of chronic diseases such as heart failure, chronic respiratory diseases, and unstable diabetes, and that many patients, including those who are not homebound, could benefit from ongoing management at home. One of these commenters stated a concern that the proposed rule focuses on costs of home care without factoring in the overall cost of care to Medicare. Another commenter urged us to appreciate the services that HHAs provide, and how home health is a cost-effective, quality alternative to rising health care costs.

Response: We appreciate the commenters' suggestions regarding broader reform associated with the home health benefit. We agree with the commenter that home health care may be an effective approach to reducing hospitalizations and overall Medicare costs. However, the commenters' suggestions are outside the scope of the proposed provisions which we solicited comments about in the CY 2010 proposed rule. The commenter is suggesting a broader scope of benefit than that which is currently statutorily mandated for Medicare's home health benefit.

Comment: A commenter felt that the actions of a few agencies are driving policy decisions for the entire home health program. The commenter was concerned about the proliferation of agencies in pockets of the country, and the negative behavior of many of these HHAs. The commenter wrote that we should work directly with States to address appropriate growth and minimize risk to Medicare without impacting access. He hopes that we will be sensitive to the impact policy decisions aimed at managing the few have on the majority of providers. Finally, the commenter appreciated our continued open dialogue through teleconferences and open door forums.

Response: Data so far suggest the problem of growing, suspect outlier payments has been associated with individual agencies and specific areas of the country. Our proposal for addressing the outlier payment problem considered the impact on agencies generally; thus, we have proposed an outlier cap at a level, 10 percent, that far exceeds the typical agency ratio with respect to outliers. We have addressed other parts of our proposed, and finalized, policies in other responses to public comments in this final regulation.

Comment: A commenter suggested we seek new types of healthcare systems and promote innovation in this area. Another commenter suggested we implement policies and guidance to maximize utilization of electronic health records and other forms of health information technology within the home health setting. Another commenter wrote that because of the HIPAA law, hospitals are not providing home health agencies with needed discharge information; this impacts the patient's transition to home and leaves the agency to rely on patient recall.

Response: CMS is aware that some home health agencies have implemented new technology to assist in patient services already. They have been able to make such investments under the current payment system. We urge continued investments in these technologies in the interests of improving care management and efficiency in the home health industry. CMS is committed to improving health setting transitions to minimize unnecessary errors and burdens on patients and providers. For example, under the QIO program, we will continue to work with the hospital industry and others to disseminate information about smoothing transitions.

III. Provisions of the Final Rule

Generally, this final rule incorporates the provisions of the August 6, 2009 proposed rule (republished on August 13, 2009 with corrected wage index tables), except as noted in the specific response to comments in the applicable section of this rule.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information (COI) requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comments on each of aforementioned issues for the information collection requirements discussed below. In this final rule, we are restating the discussion of the information collection requirements as it appeared in the HH PPS proposed rule published on August 13, 2009 (74 FR 40948).

A. ICRs Regarding the Requirements for Home Health Services

In § 424.22 we stated that if a patient's underlying condition or complication required a registered nurse to ensure that essential non-skilled care was achieving its purpose, and necessitated a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician would include a written narrative describing the clinical justification of this need.

The burden associated with this requirement will be the time and effort put forth by the physician to include the written narrative. We estimate it will take one physician approximately 5 minutes to meet this requirement. We estimate the frequency of such a situation to occur in about 5 percent of episodes (or about 345,600 episodes a year); therefore, the total annual burden associated with this requirement will be 28,800 hours for CY 2010.

Comment: Two commenters wrote that the time and burden estimates presented in section IV. of the proposed rule were underestimated. One noted that these regulations would increase costs of operation. For section IV.A., the other wrote that the time to educate the physician regarding the type of documentation needed to support unlicensed care from a Management and Evaluation perspective would be astronomical, in addition to the time required trying to obtain the documentation from the physician. She added that the time physicians must spend collecting information on each client to document medical necessity was greater than 5 minutes.

Response: We disagree that the time to educate the physician regarding the type of documentation that would be needed to fulfill the requirement for a physician's written narrative, in these rare instances, as astronomical. Nor do we agree that the time required to obtain the narrative will be excessive. The physician should already have considered what his/her clinical justification is for the certification or recertification of the beneficiary to receive Medicare's home health benefit, as well as the ordering and approving of these skilled services on the plan of care. Consequently, the physician should have already synthesized their clinical justification, and need only to record it into the certification or recertification.

The requirements and associated information collection burden contained in § 424.22 will be submitted to OMB for approval. As part of the approval process, we will seek public comments in an additional notice separate from this final rule.

B. ICRs Regarding Deactivation of Medicare Billing Privileges

In § 424.540(b)(3)(i), an HHA whose Medicare billing privileges are deactivated under the provisions found in § 424.540(a) must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privilege can be reactivated. The burden associated with this requirement will be the time and effort put forth by the HHA to obtain a State survey or accreditation. We estimate it will take the prospective provider/owner 60 hours to obtain a State survey or accreditation. We estimate that there will be 2,000 such occurrences annually. (We believe that this figure is an extremely high-end estimate, but will utilize it for purposes of this final rule so as to ensure that we do not underestimate the potential burden on HHAs. Therefore, the total annual burden associated with this requirement will be 120,000 hours.

Comment: Two commenters wrote that the time and burden estimates presented in section IV. of the proposed rule were underestimated. One noted that these regulations would increase costs of operation. For section IV.B, a commenter wrote that the time required to receive an initial survey was months from an accrediting organization since in her State, the State survey agency was no longer performing initial surveys.

Response: With respect to the estimated survey timeframe, the calculation is based on the total amount of time the provider spends: (1) In undertaking specific activities in preparation for the survey, and (2) undergoing the survey itself. The calculation does not include the time waiting for the survey to take place.

The requirements and associated information collection burden contained in § 424.540(b)(3) will be submitted to OMB for approval. As part of the approval process, we will seek public comments in an additional notice separate from this final rule.

C. ICRs Regarding Prohibition Against Sale or Transfer of Billing Privileges

At § 424.550(b)(1) we require that an HHA undergoing an ownership change will have to obtain an initial State survey or accreditation by an approved accreditation organization if the change takes place within 36 months after the effective date of the HHA's participation in Medicare. Between April 2008 and April 2009, approximately 2,000 Medicare-enrolled HHAs—or 22.5 percent of the 9,000 total number of HHAs enrolled in Medicare—underwent a change of ownership. Naturally, the magnitude of the ownership changes varied by HHA, but the fact that almost one-quarter of all Medicare-enrolled HHAs changed ownership in some form within the past year is, for the reasons outlined in the preamble to this rule, significant.

It is also important to note that of the 2,000 ownership changes, approximately 20 percent occurred in Texas, another 20 percent in Florida, and 14 percent in California, meaning that over one-half of all changes in ownership occurred in three States. Though it is likely that, once this provision is implemented, the number of total annual ownership changes will decrease, we will assume for purposes of this final rule that the figure of 2,000 will remain constant so as to ensure that we do not underestimate the potential burden on HHAs.

The burden associated with this requirement in § 424.550(b)(1) is twofold. First, the HHA will need to complete and submit a Medicare enrollment application (paper or electronic) as an initial applicant. This can be done electronically via the Internet-Based Provider Enrollment, Chain and Ownership System (PECOS) or by using the paper CMS–855 enrollment application. The estimated burden of completing the entire application as a new enrollee is 3 hours. Thus, the estimated annual burden for the approximately 2,000 HHAs that will change ownership will be 6,000 hours. Second, the provider will need to undergo a survey (or obtain accreditation in lieu of a survey) and perform administrative activities associated therewith. We estimate that the total hourly burden to the HHA for stated activities will be 60 hours, for an annual burden of 120,000 hours (2,000 HHAs × 60 hours).

Therefore, we estimate that the total annual burden of compliance with § 424.550(b)(1) will be 126,000 hours (120,000 hours + 6,000 hours).

The requirements and associated information collection burden contained in § 424.550(b)(1) will be submitted to OMB for approval. As part of the approval process, we will seek public comments in an additional notice separate from this final rule.

Comment: Two commenters wrote that the time and burden estimates presented in section IV. of the proposed rule were underestimated. One noted that these regulations would increase costs of operation. For section IV.C, one of the commenters believed that the time to complete the enrollment form needed when a sale/transfer of ownership occurs is far greater than 3 hours, taking several days to complete the form and gather all required documentation. Additionally, if a deficiency in completing this complex form is noted, the time to correct it is not factored in.

Response: We believe that the timeframe we have used for the completion of the form is both accurate and consistent with past estimates that CMS has used for the completion of the Medicare enrollment application (for example, CMS–855A).

D. ICRs Regarding Patient Assessment Data

Section 484.210 will require an HHA to submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230 and 484.235.

The burden associated with this is the time and effort put forth by the HHA to submit the OASIS data. This burden is currently accounted for under OMB# 0938–0761.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden hours
0938–NEW	424.22	345,600	1/12	28,800.
None	424.540(b)(3)(i)	2,000	60	120,000.
None	424.550(b)(1)	2,000	63	126,000.
0938–0761	484.210	N/A	N/A	N/A.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1560–F, Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov*.

E. ICRs Regarding Annual Update of the Unadjusted National Prospective 60-Day Episode Payment Rate

Section 484.225(i) requires the submission of quality measures as specified by the Secretary. As part of this requirement, each HHA sponsoring a Home Health Care CAHPS (HHCAHPS) Survey must prepare and submit to its survey vendor a file containing patient data on patients served the preceding month that will be used by the survey vendor to select the sample and field the survey. This file (essentially the sampling frame) for most home health agencies can be generated from existing databases with minimal effort. For some small HHAs, preparation of a monthly sample frame may require more time. However, data elements needed on the sample frame will be kept at a minimum to reduce the burden on all HHAs.

The burden associated with this requirement is the time and effort put forth by the HHA to prepare and submit the file containing patient data on patients. The survey instrument and procedures for completing the instrument are designed to minimize burden on all respondents. No significant burden is expected for small agencies beyond providing their contracted vendor with a monthly file of patients served.

Initially, we estimate it will take one HHA 5 hours for the first month to meet this requirement. The subsequent monthly burden is estimated to be 30 minutes per HHA. We estimate approximately 7,000 HHAs will be submitting this data annually. Based on that number, the burden associated with the first month is estimated at 35,000 hours. The burden will decrease to 2,100 for subsequent months. Therefore, the total annual burden for the first year will total 58,100.

The burden associated with the home health patient's submission of the HHCAHPS survey is currently pending OMB approval (CMS–10275/OMB# 0938–NEW). Once OMB approval has been obtained, we will revise the package to include the burden on the HHAs as discussed above.

Comment: Two commenters wrote that the time and burden estimates presented in section IV of the proposed rule were underestimated. One noted that these regulations would increase costs of operation. For section IV.E on the HHCAHPS, one commenter wrote that time and burden were severely underestimated as HHAs must implement both procedural and technological changes which are not included in the estimates.

Response: In the beginning, it will take HHAs a little time to set up their files to retrieve the needed patient information on a monthly basis for their respective survey vendors. However, from several years of experience with Hospital CAHPS, we have observed that the participating hospitals are able to deliver their monthly files to their respective survey vendors *with minimal effort.* Regarding section IV.E of the Information Collections Requirements, CMS is adopting three changes to the proposed HHCAHPS implementation that may alleviate some of the ''burden'': (1) Delayed HHCAHPS linkage to CY 2012 payment and not to CY 2011 payment; (2) the eligible patient list that HHAs need to give to their survey vendors include only Medicare and/or Medicaid patients; (3) HHAs may give V Codes to their survey vendors if ICD–9 codes are unavailable; (4) HHAs will have the opportunity to voluntarily implement HHCAHPS for a year (October 2009 through September 2010) for ''practicing'' the implementation procedures before data collection ''counts'' toward an annual payment update.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis, which to the best of our ability, presents the costs and benefits of the rulemaking.

1. HHA Provisions Regarding Ownership Changes and Reactivation of Billing Privileges

For the proposed rule, we estimated that a total of 2,000 deactivated HHAs and 2,000 HHAs undergoing a change of ownership may be affected annually by our proposed payment safeguard provisions. Yet we believe that the actual budgetary impact will be minimal, as these estimated figures were very high-end estimates and were used so as not to underestimate the potential burden on HHAs. The reality is that the annual number of deactivated HHAs that will seek to reactivate their billing privileges will very likely be substantially less than 2,000. This is primarily because the requirements in 42 CFR 424.540(b)(3)(i) will encourage some deactivated HHAs to remain in a deactivated status rather than undergo a State survey, especially if they plan to only infrequently bill Medicare after the reactivation of their Medicare billing privileges. It is for this same reason that we believe that the number of ownership changes will be less than 2,000. Some entities and individuals

may be reluctant to sell or buy a Medicare-enrolled HHA if they know that the HHA will first have to undergo an initial Medicare enrollment and survey. While it is not possible for us to place a precise figure on the number of HHAs that will forgo reactivation or an ownership change due to the survey requirement, we do believe that it will be significant enough to mitigate the overall budgetary impact.

Moreover, and as previously stated, we believe that these changes are necessary to ensure that currently enrolled and prospective HHAs are billing for the services provided and are in compliance with the conditions of participation in 42 CFR Part 484, and all other Medicare requirements.

As for the issue of beneficiary access, the number of affected HHAs is such that we do not believe that beneficiaries will be adversely impacted by these provisions. To the contrary, any reduction in the number of enrolled HHAs that will result from the implementation of these provisions will be more than offset by the assurance that those HHAs that cannot meet Medicare requirements and quality standards are no longer in the program.

We are unable to determine the exact extent to which currently enrolled and prospective HHAs would be able to meet the requirements outlined in the provisions. In addition, as a result of a dearth of quantifiable data, we cannot effectively derive an estimate of the monetary impacts of these provisions. Accordingly, we are seeking public comment so that the public may provide any data available that provides a calculable impact or any alternative to these provisions.

2. CY 2010 Update

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2010. Accordingly, the following analysis describes the impact in CY 2010 only. We estimate that the net impact of the proposals in this rule, including a 2.75 percent reduction to the national standardized 60-day episode payment rates and the NRS conversion factor to account for the case-mix change adjustment, is approximately $140 million in CY 2010 savings. The estimated $140 million impact reflects the distributional effects of an updated wage index (–$10 million) as well as the final 2.0 percent home health market basket increase (an additional $350 million in CY 2010 expenditures attributable only to the CY 2010 home health market basket), and the 2.75 percent decrease (–$480 million for the third year of a 4-year phase-in) to the HH PPS national standardized 60-day episode rates and the NRS conversion factors to account for the case-mix change adjustment under the HH PPS. The $140 million is reflected in column 5 of Table 7 as a 1.03 percent decrease in expenditures when comparing the current CY 2009 system to the CY 2010 system.

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 $7 million to $34.5 million in any 1 year. For the purposes of the RFA, approximately 75 percent of HHAs are considered to 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. Excluding HHAs in areas of the country where high and suspect outlier payments exist, this rule is estimated to have an overall positive effect upon small entities (see section V.B ''Anticipated Effects'', of this final rule, for supporting analysis).

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 the 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 rule applies to home health agencies. Therefore, the Secretary has determined that this rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of about $100 million or more in 1995 dollars, updated for inflation. That threshold is currently approximately $133 million in 2009. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or by the private sector, of $133 million or more.

Executive Order 13132 established certain requirements that an agency must meet when it promulgates a 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 will not have substantial direct effects on the rights, roles, and responsibilities of States, local, or tribal governments.

B. Anticipated Effects

This final rule sets forth updates to the HH PPS rates contained in the CY 2009 notice (73 FR 65351, November 3, 2008). The impact analysis of this final rule presents the estimated expenditure effects of policy changes 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 2007. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the BBA, the BBRA, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the MMA, the DRA, MIPPA, ARRA, 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.

Table 7 represents how home health agency revenues are likely to be affected by the policy changes described 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 2007. Column one of this table classifies HHAs according to a number of characteristics including provider type, geographic region, and urban versus rural location.

For the purposes of analyzing impacts on payments, we performed three simulations and compared them to each other. Based on our assumption that

outliers, as a percentage of total HH PPS payments, will be no more than 5 percent in CY 2009, the 2009 baseline, for the purposes of these simulations, we assumed that the full 5 percent outlay for outliers will be paid under our policy in 2009 of a 0.89 FDL ratio. As described in section III.A. of this final rule, given our CY 2010 policies of a 0.67 FDL ratio and a 10 percent cap on outlier payments, we will return 2.5 percent back into the national standardized 60-day episode payment rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor, and then estimate outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010. All three simulations use a CBSA-based wage index reported on the 2007 claims to determine the appropriate wage index.

The first simulation estimates CY 2009 payments under the current system (to include the 2009 wage index). The second simulation estimates CY 2009 payments under the current system, but with the 2010 wage index. The second simulation produces an estimate of what total payments using the sample data will have been in CY 2009 without any of the provisions in this rule, except for that of the 2010 wage index. The third simulation estimates CY 2010 payments with the 2010 wage index, incorporating our maintaining of the 2.75 percent reduction to the HH PPS rates, as well as all the provisions of this rule.

These simulations demonstrate the effects of: a new 2010 wage index, a 2.75 percent reduction to account for the increase in nominal case-mix, a 2.0 percent market basket update, a 2.5 percent increase to account for a new outlier target of 2.5 percent, a 0.67 FDL ratio, and a 10 percent cap on outlier payments. Specifically, the second column of Table 7 shows the percent change due to the effects of the 2010 wage index. The third column of Table 7 shows the percent change due to the combined effects of the 2010 wage index, our maintaining of a 2.75 percent reductions to the rates to account for the increase in nominal case-mix, the 2.0 percent home health market basket update, the 2.5 percent increase to the HH PPS rates to account for an approximate 2.5 percent target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, and a 10 percent outlier cap.

The overall percentage change, for all HHAs, in estimated total payments from CY 2009 to CY 2010 is a decrease of approximately 1.03 percent. Rural HHAs, however, are estimated to see an increase in payments from CY 2009 to CY 2010 of about 3.27 percent. On the other hand, urban HHAs are expected to see a decrease of approximately 1.81 percent in payments from CY 2009 to CY 2010.

Voluntary non-profit HHAs (3.36 percent), facility-based HHAs (3.72 percent), and government owned HHAs (2.94 percent) are estimated to see an increase in the percentage change in estimated total payments from CY 2009 to CY 2010. Proprietary and freestanding HHAs, on the other hand, are estimated to see decreases of 3.32 percent and 1.90 percent, respectively, in estimated total payments from CY 2009 to CY 2010. Freestanding HHAs, broken out, show that voluntary non-profit and governmental HHAs are estimated to see increases of 3.47 percent and 3.48 percent, respectively, in estimated total payments from CY 2009 to CY 2010.

HHAs in the North and Midwest regions are expected to experience a percentage change increase in the estimated total payments from CY 2009 to CY 2010 of 3.66 percent and 3.48 percent, respectively. HHAs in the South and West regions of the country are estimated to experience decreases in the percentage change in estimated total payments from CY 2009 to CY 2010 of 4.19 percent and 1.70 percent. We believe that the major contributors to the estimated decreases in payments in these areas of the country are those with high and suspect outlier payments.

Breaking this down even further, it is estimated that New England, Mid Atlantic, East South Central, East North Central, West North Central, and Mountain area HHAs are all expected to experience increases in their payments in CY 2010 ranging from almost 2 percent to almost 5 percent. Conversely, South Atlantic and Pacific HHAs are expected to experience decreases, 11.84 percent and 3.09 percent respectively, in the percentage change in estimated total payments from CY 2009 to CY 2010. Again, we believe that the major contributors to the estimated decreases in payments in these areas of the country are those with high and suspect outlier payments.

The last section of Table 7 shows the percentage change in payments by agency size, as determined by the number of first episodes. The agency size categories, for this rule, are based on the number of first episodes in a random 20 percent beneficiary sample of CY 2007 claims data. Initial episodes, under the HH PPS, are defined as the first episode in a series of adjacent episodes (contiguous episodes that are separated by no more than a 60-day period between episodes) for a given beneficiary. Initial, or first, episodes are a good estimate of agency size, because this method approximates the number of admissions experienced by the agency based on approximately one-fifth of the total annual data. The size categories were set to have roughly equal numbers of agencies, except that the highest category has somewhat more agencies because added detail amongst the large size category was not needed. As such, the size categories for these impact analyses are: less than 19 first episodes, 20 to 49 first episodes, 50 to 99 first episodes, 100 to 199 first episodes, and 200 or more first episodes. Larger HHAs (those with 200 or more Medicare home health initial episodes per year) are estimated to experience an increase in payments from CY 2009 to CY 2010 of approximately 2.27 percent. Mid-size to small agencies are expected to see a decrease in their payments in CY 2010, ranging from 1.95 percent to 16.08 percent. However, we believe that the major contributors to the estimated decreases in payments for mid-size to small agencies are those agencies in areas of the country with high and suspect outlier payments. Consequently, as we did in the proposed rule, we have provided a more detailed discussion, and analysis in Table 8 below, that demonstrates where, in the country, these estimated large decreases for mid-size to small agencies are occurring.

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Table 7: IMPACT BY AGENCY TYPE

Group	Comparisons	
	Percent change due to the effects of the updated wage index only	Impact of CY 2010 Policies[1]
Type of Facility		
Free-Standing/Other Vol/NP	0.00%	3.07%
Free-Standing/Other Proprietary	-0.05%	-3.45%
Free-Standing/Other Government	-0.32%	2.47%
Facility-Based Vol/NP	-0.12%	3.78%
Facility-Based Proprietary	-0.22%	3.48%
Facility-Based Government	-0.27%	3.47%
Subtotal: Freestanding	-0.04%	-1.90%
Subtotal: Facility-based	-0.15%	3.72%
Subtotal: Vol/NP	-0.05%	3.36%
Subtotal: Proprietary	-0.05%	-3.32%
Subtotal: Government	-0.30%	2.94%
TOTAL	-0.06%	-1.03%
Type of Facility (Rural * Only)		
Free-Standing/Other Vol/NP	-0.44%	3.47%
Free-Standing/Other Proprietary	-0.14%	3.10%
Free-Standing/Other Government	-0.57%	3.48%
Facility-Based Vol/NP	-0.44%	3.50%
Facility-Based Proprietary	-0.61%	2.75%
Facility-Based Government	-0.42%	3.56%
Type of Facility (Urban * Only)		

Free-Standing/Other Vol/NP	0.06%	3.01%
Free-Standing/Other Proprietary	-0.03%	-4.35%
Free-Standing/Other Government	-0.04%	1.33%
Facility-Based Vol/NP	-0.04%	3.85%
Facility-Based Proprietary	0.03%	3.94%
Facility-Based Government	-0.03%	3.33%
Type of Facility (Urban* or Rural*)		
Rural	-0.30%	3.27%
Urban	-0.02%	-1.81%
TOTAL	-0.06%	-1.03%
Facility Location: Region*		
North	0.06%	3.66%
South	-0.05%	-4.19%
Midwest	-0.23%	3.48%
West	-0.07%	-1.70%
Outlying	0.37%	4.26%
TOTAL	-0.06%	-1.03%
Facility Location: Area of the Country		
New England	0.56%	4.78%
Mid Atlantic	-0.21%	3.05%
South Atlantic	0.27%	-11.84%
East South Central	-0.23%	3.53%
West South Central	-0.29%	0.23%
East North Central	-0.27%	3.44%
West North Central	-0.07%	3.66%
Mountain	0.34%	1.91%
Pacific	-0.23%	-3.09%
Outlying	0.37%	4.26%
TOTAL	-0.06%	-1.03%
Facility Size: (Number of First Episodes)		
< 19	0.12%	-16.08%
20 to 49	0.03%	-11.78%
50 to 99	-0.03%	-9.20%
100 to 199	-0.12%	-1.95%
200 or More	-0.07%	2.27%
TOTAL	-0.06%	-1.03%

Note: Based on a 20% sample of CY 2007 claims linked to OASIS assessments.
*Urban / rural status, for the purposes of these simulations, is based on the wage index on which episode payment is based. The wage index is based on the site of service of the beneficiary.

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

[1] **Percent change due to the effects of the update wage index, the 2.0% home health market basket update, the 2.75% reduction to the national standardized episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor for nominal increase in case-mix, the 2.5% increase in the rates due to the new approximate 2.5% target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, and a 10% outlier cap**

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Given the overall large negative impact observed by smaller agencies, we performed more detailed analysis targeted at identifying where the large negative impacts were occurring. Table 8 below presents the results of the regional analysis for small agencies. Column 1, of Table 8, shows the regional and agency size classifications similar to those in Table 7. In column 2 we repeat the overall impacts (from Table 7) for those classifications. In columns 3 through 7, we drill down in our analysis, looking at those classifications by the size of the agency (as defined by the number of first episodes). It is clear from this analysis that, for smaller agencies, the vast majority of the negative impact is occurring in areas of the country (such as the South and South Atlantic) where there exist high and suspect outlier payments. Specifically, in columns 3, 4, and 5 of Table 8, for the South Atlantic area of the country (which includes Miami-Dade, Florida), the negative percentage impacts in payment ranging from around 40 percent to just over 53 percent are evidence that it is the high and suspect outlier payments in areas such as this, that are skewing the results of the overall impact analysis. Estimated impacts for small agencies in the South (negative impacts ranging around 15 percent to 22 percent) and the Pacific (negative impacts ranging from around 12 percent to 17 percent) areas of the country, reflect similar results. Conversely, small HHAs in most other parts of the country are estimated to see increases in payments in CY 2010, ranging from 0.20 percent to almost 5 percent. Consequently, we believe that small HHAs without high and suspect outlier payments, on average, will see a positive impact on their payments in CY 2010. We do not believe there will be any significant impact on beneficiaries, as a result of the provisions of this rule. Areas where negative impacts have been estimated for HHAs, are primarily urban, and thus we believe that beneficiaries have a reasonable pool of HHAs from which to receive home health services.

Table 8: SMALL AGENCY IMPACTS

Group	Comparison of 2009-2010 Changes					
	Overall	< 20 Episodes	20-49 episodes	50-99 episodes	100-199 episodes	200 or more episodes
Facility Location: Region of the Country						
North	3.66%	0.10%	2.96%	2.95%	3.59%	3.71%
South	-4.19%	-22.08%	-17.60%	-14.86%	-3.85%	1.10%
Midwest	3.48%	2.46%	3.27%	3.33%	3.60%	3.56%
West	-1.70%	-5.83%	-10.37%	-9.32%	-3.95%	1.78%
Outlying	4.26%	4.30%	4.21%	4.68%	4.21%	4.25%
TOTAL	-1.03%	-16.08%	-11.78%	-9.20%	-1.95%	2.27%
Facility Location: Region of the Country (Census Region)						
New England	4.78%	-3.24%	3.40%	4.73%	3.99%	4.93%
Mid Atlantic	3.05%	3.77%	2.53%	1.26%	3.13%	3.08%
South Atlantic	-11.84%	-53.37%	-45.96%	-40.61%	-16.63%	-0.78%
East South Central	3.53%	3.90%	2.11%	3.72%	3.05%	3.60%
West South Central	0.23%	-5.81%	-2.73%	-1.44%	1.49%	2.08%
East North Central	3.44%	2.27%	3.02%	3.41%	3.70%	3.50%
West North Central	3.66%	3.90%	4.54%	3.00%	3.28%	3.80%
Mountain	1.91%	1.44%	-1.54%	1.35%	1.63%	2.80%
Pacific	-3.09%	-11.54%	-16.84%	-13.28%	-6.72%	1.46%
Outlying	4.26%	4.30%	4.21%	4.68%	4.21%	4.25%
TOTAL	-1.03%	-16.08%	-11.78%	-9.20%	-1.95%	2.27%
Facility Size (Number of First Episodes)						
< 19 episodes	-16.08%	-16.08%				
20 to 49	-11.78%		-11.78%			
50 to 99	-9.20%			-9.20%		
100 to 199	-1.95%				-1.95%	
200 or More	2.27%					2.27%
TOTAL	-1.03%	-16.08%	-11.78%	-9.20%	-1.95%	2.27%

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

C. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the classification of the expenditures associated with the provisions of this rule.

Table 9, below provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $140 million.

TABLE 9—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2009 HH PPS CALENDAR YEAR TO THE 2010 HH PPS CALENDAR YEAR

Category	Transfers
Annualized Monetized Transfers.	Negative transfer—Estimated decrease in expenditures: $140 million.
From Whom to Whom.	Federal Government to HH Providers.

D. Conclusion

In conclusion, we estimate that the net impact of the proposals in this rule, including a 2.75 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor to account for the case-mix change adjustment, is approximately $140 million in CY 2010 savings. The $140 million impact reflects the distributional effects of an updated wage index (−$10 million) as well as the final 2.0 percent home health market basket increase (an additional $350 million in CY 2010 expenditures attributable only to the CY 2010 home

health market basket), and the 2.75 percent decrease (−$480 million for the third year of a 4-year phase-in) to the national standardized 60-day episode rates and the NRS conversion factor to account for the case-mix change adjustment under the HH PPS. This analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 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).

■ 2. Section 409.42 is amended by revising paragraph (c)(1) to read as follows:

§ 409.42 Beneficiary qualifications for coverage of services.

* * * * *

(c) * * *

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32. (Also see § 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.) These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

* * * * *

■ 3. Section 409.43 is amended by revising paragraph (e)(1)(ii) to read as follows:

§ 409.43 Plan of care requirements.

* * * * *

(e) * * *

(1) * * *

(ii) Significant change in condition; or

* * * * *

■ 4. Section 409.44 is amended by revising the introductory text of paragraph (b)(1) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

(b) * * *

(1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.4 of this chapter, meet the criteria for skilled nursing services specified in § 409.32, and meet the qualifications for coverage of skilled services specified in § 409.42(c). See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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

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

■ 6. Section 424.22 is amended as follows:

■ A. Revising paragraph (a)(1)(i);

■ B. Revising paragraph (b)(2).

§ 424.22 Requirements for home health services.

(a) * * *

(1) * * *

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

* * * * *

(b) * * *

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy

may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

* * * * *

■ 7. Section 424.540 is amended by revising paragraph (b)(3) to read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

* * * * *

(b) * * *

(3) Except as provided in paragraph (b)(3)(i) of this section, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at paragraph (a) of this section must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

* * * * *

■ 8. Section 424.550 is amended by adding paragraph (b)(1) and adding and reserving paragraph (b)(2), to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(1) If an owner of a home health agency sells (including asset sales or stock transfers), transfers or relinquishes ownership of the HHA within 36 months after the effective date of the HHA's enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

(i) Enroll in the Medicare program as a new HHA under the provisions of § 424.510, and

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2) [Reserved]

* * * * *

PART 484—HOME HEALTH SERVICES

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

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

Subpart C—Furnishing of Services

■ 10. Section 484.55 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(ii) Significant change in condition; or

* * * * *

Subpart E—Prospective Payment System for Home Health Agencies

■ 11. Section 484.210 is amended by revising paragraph (e) to read as follows:

§ 484.210 Data used for the calculation of the national prospective 60-day episode payment.

* * * * *

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix. An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230 and 484.235.

■ 12. Revise § 484.250 to read as follows:

§ 484.250 Patient assessment data.

An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235.

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 15, 2009.*

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: *October 29, 2009.*

Kathleen Sebelius,

Secretary.

Note: The following addenda will not be published in the Code of Federal Regulations.

BILLING CODE 4120–01–P

ADDENDUM A. CY 2010 WAGE INDEX FOR RURAL AREAS BY CBSA; APPLICABLE PRE-FLOOR AND PRE-RECLASSIFIED HOSPITAL WAGE INDEX

CBSA Code	Nonurban Area	Wage Index
01	Alabama	0.7327
02	Alaska	1.1669
03	Arizona	0.8790
04	Arkansas	0.7332
05	California	1.2051
06	Colorado	0.9929
07	Connecticut	1.1093
08	Delaware	0.9910
10	Florida	0.8566
11	Georgia	0.7623
12	Hawaii	1.1113
13	Idaho	0.7733
14	Illinois	0.8312
15	Indiana	0.8529
16	Iowa	0.8624
17	Kansas	0.8167
18	Kentucky	0.7813
19	Louisiana	0.7611
20	Maine	0.8579

CBSA Code	Nonurban Area	Wage Index
21	Maryland	0.9131
22	Massachusetts[1]	1.1700
23	Michigan	0.8778
24	Minnesota	0.9160
25	Mississippi	0.7638
26	Missouri	0.7671
27	Montana	0.8399
28	Nebraska	0.8705
29	Nevada	0.9674
30	New Hampshire	0.9957
31	New Jersey[1]	------
32	New Mexico	0.8938
33	New York	0.8269
34	North Carolina	0.8535
35	North Dakota	0.7813
36	Ohio	0.8506
37	Oklahoma	0.7654
38	Oregon	1.0236
39	Pennsylvania	0.8306
40	Puerto Rico[1]	0.4047
41	Rhode Island[1]	------
42	South Carolina	0.8394
43	South Dakota	0.8510

1 All counties within the State are classified as urban, with the exception of Massachusetts and Puerto Rico. Massachusetts and Puerto Rico have areas designated as rural, however, no short-term, acute care hospitals are located in the area(s) for CY 2010

CBSA Code	Nonurban Area	Wage Index
44	Tennessee	0.7808
45	Texas	0.7759
46	Utah	0.8363
47	Vermont	0.9763
48	Virgin Islands	0.7416
49	Virginia	0.7869
50	Washington	1.0224
51	West Virginia	0.7396
52	Wisconsin	0.9206
53	Wyoming	0.9535
65	Guam	0.9611

ADDENDUM B.- CY 2010 WAGE INDEX FOR URBAN AREAS BY CBSA; APPLICABLE PRE-FLOOR AND PRE-RECLASSIFIED HOSPITAL WAGE INDEX

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10180	Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX	0.7946
10380	Aguadilla-Isabela-San Sebastián, PR Aguada Municipio, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR	0.3462

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10420	Akron, OH Portage County, OH Summit County, OH	0.8850
10500	Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA	0.8899
10580	Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY	0.8777
10740	Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM	0.9399
10780	Alexandria, LA Grant Parish, LA Rapides Parish, LA	0.8012
10900	Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA	0.9611
11020	Altoona, PA Blair County, PA	0.8863
11100	Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX	0.8689
11180	Ames, IA Story County, IA	0.9493

CBSA Code	Urban Area (Constituent Counties)	Wage Index
11260	Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK	1.2013
11300	Anderson, IN Madison County, IN	0.9052
11340	Anderson, SC Anderson County, SC	0.9023
11460	Ann Arbor, MI Washtenaw County, MI	1.0293
11500	Anniston-Oxford, AL Calhoun County, AL	0.7643
11540	Appleton, WI Calumet County, WI Outagamie County, WI	0.9289
11700	Asheville, NC Buncombe County, NC Haywood County, NC Henderson County, NC Madison County, NC	0.9057
12020	Athens-Clarke County, GA Clarke County, GA Madison County, GA Oconee County, GA Oglethorpe County, GA	0.9492

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12060	Atlanta-Sandy Springs-Marietta, GA Barrow County, GA Bartow County, GA Butts County, GA Carroll County, GA Cherokee County, GA Clayton County, GA Cobb County, GA Coweta County, GA Dawson County, GA DeKalb County, GA Douglas County, GA Fayette County, GA Forsyth County, GA Fulton County, GA Gwinnett County, GA Haralson County, GA Heard County, GA Henry County, GA Jasper County, GA Lamar County, GA Meriwether County, GA Newton County, GA Paulding County, GA Pickens County, GA Pike County, GA Rockdale County, GA Spalding County, GA Walton County, GA	0.9591
12100	Atlantic City-Hammonton, NJ Atlantic County, NJ	1.1554
12220	Auburn-Opelika, AL Lee County, AL	0.8138

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12260	Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC	0.9409
12420	Austin-Round Rock, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX	0.9518
12540	Bakersfield, CA Kern County, CA	1.1232
12580	Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD	1.0214
12620	Bangor, ME Penobscot County, ME	1.0154
12700	Barnstable Town, MA Barnstable County, MA	1.2618

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12940	Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA	0.8180
12980	Battle Creek, MI Calhoun County, MI	1.0000
13020	Bay City, MI Bay County, MI	0.9267
13140	Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX	0.8383
13380	Bellingham, WA Whatcom County, WA	1.1395
13460	Bend, OR Deschutes County, OR	1.1446
13644	Bethesda-Frederick-Rockville, MD Frederick County, MD Montgomery County, MD	1.0298
13740	Billings, MT Carbon County, MT Yellowstone County, MT	0.8781
13780	Binghamton, NY Broome County, NY Tioga County, NY	0.8780

CBSA Code	Urban Area (Constituent Counties)	Wage Index
13820	Birmingham-Hoover, AL Bibb County, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL	0.8554
13900	Bismarck, ND Burleigh County, ND Morton County, ND	0.7637
13980	Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA	0.8394
14020	Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN	0.9043
14060	Bloomington-Normal, IL McLean County, IL	0.9378
14260	Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID	0.9318
14484	Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA	1.2186
14500	Boulder, CO Boulder County, CO	1.0266
14540	Bowling Green, KY Edmonson County, KY Warren County, KY	0.8469
14600	Bradenton-Sarasota-Venice, FL	0.9735

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	Manatee County, FL Sarasota, FL	
14740	Bremerton-Silverdale, WA Kitsap County, WA	1.0755
14860	Bridgeport-Stamford-Norwalk, CT Fairfield County, CT	1.2792
15180	Brownsville-Harlingen, TX Cameron County, TX	0.9020
15260	Brunswick, GA Brantley County, GA Glynn County, GA McIntosh County, GA	0.9178
15380	Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY	0.9740
15500	Burlington, NC Alamance County, NC	0.8749
15540	Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT	1.0106
15764	Cambridge-Newton-Framingham, MA Middlesex County, MA	1.1278
15804	Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ	1.0374
15940	Canton-Massillon, OH Carroll County, OH Stark County, OH	0.8813
15980	Cape Coral-Fort Myers, FL Lee County, FL	0.9076
16020	Cape Girardeau-Jackson, MO-IL Alexander County, IL Bollinger County, MO Cape Girardeau County, MO	0.9047
16180	Carson City, NV Carson City, NV	1.0531

CBSA Code	Urban Area (Constituent Counties)	Wage Index
16220	Casper, WY Natrona County, WY	0.9520
16300	Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA	0.8984
16580	Champaign-Urbana, IL Champaign County, IL Ford County, IL Piatt County, IL	1.0108
16620	Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV	0.8141
16700	Charleston-North Charleston-Summerville, SC Berkeley County, SC Charleston County, SC Dorchester County, SC	0.9279
16740	Charlotte-Gastonia-Concord, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC	0.9474

CBSA Code	Urban Area (Constituent Counties)	Wage Index
16820	Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA	0.9372
16860	Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN	0.8831
16940	Cheyenne, WY Laramie County, WY	0.9344
16974	Chicago-Naperville-Joliet, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL	1.0471
17020	Chico, CA Butte County, CA	1.1198

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17140	Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH	0.9483
17300	Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN	0.7980
17420	Cleveland, TN Bradley County, TN Polk County, TN	0.7564
17460	Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH	0.8914

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17660	Coeur d'Alene, ID Kootenai County, ID	0.9235
17780	College Station-Bryan, TX Brazos County, TX Burleson County, TX Robertson County, TX	0.9498
17820	Colorado Springs, CO El Paso County, CO Teller County, CO	0.9821
17860	Columbia, MO Boone County, MO Howard County, MO	0.8618
17900	Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC	0.8789
17980	Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscogee County, GA	0.8724
18020	Columbus, IN Bartholomew County, IN	0.9536

CBSA Code	Urban Area (Constituent Counties)	Wage Index
18140	Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH	1.0101
18580	Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX	0.8693
18700	Corvallis, OR Benton County, OR	1.1002
19060	Cumberland, MD-WV Allegany County, MD Mineral County, WV	0.8045
19124	Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX	0.9853
19140	Dalton, GA Murray County, GA Whitfield County, GA	0.8666
19180	Danville, IL Vermilion County, IL	0.8738

CBSA Code	Urban Area (Constituent Counties)	Wage Index
19260	Danville, VA Pittsylvania County, VA Danville City, VA	0.8323
19340	Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA	0.8284
19380	Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH	0.9211
19460	Decatur, AL Lawrence County, AL Morgan County, AL	0.7799
19500	Decatur, IL Macon County, IL	0.7995
19660	Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL	0.8865
19740	Denver-Aurora-Broomfield, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO	1.0731

CBSA Code	Urban Area (Constituent Counties)	Wage Index
19780	Des Moines-West Des Moines, IA Dallas County, IA Guthrie County, IA Madison County, IA Polk County, IA Warren County, IA	0.9649
19804	Detroit-Livonia-Dearborn, MI Wayne County, MI	0.9729
20020	Dothan, AL Geneva County, AL Henry County, AL Houston County, AL	0.7406
20100	Dover, DE Kent County, DE	0.9931
20220	Dubuque, IA Dubuque County, IA	0.8869
20260	Duluth, MN-WI Carlton County, MN St. Louis County, MN Douglas County, WI	1.0448
20500	Durham-Chapel Hill, NC Chatham County, NC Durham County, NC Orange County, NC Person County, NC	0.9618
20740	Eau Claire, WI Chippewa County, WI Eau Claire County, WI	0.9567
20764	Edison-New Brunswick, NJ Middlesex County, NJ Monmouth County, NJ Ocean County, NJ Somerset County, NJ	1.1061
20940	El Centro, CA Imperial County, CA	0.8766
21060	Elizabethtown, KY Hardin County, KY Larue County, KY	0.8388

CBSA Code	Urban Area (Constituent Counties)	Wage Index
21140	Elkhart-Goshen, IN Elkhart County, IN	0.9489
21300	Elmira, NY Chemung County, NY	0.8341
21340	El Paso, TX El Paso County, TX	0.8541
21500	Erie, PA Erie County, PA	0.8779
21660	Eugene-Springfield, OR Lane County, OR	1.1034
21780	Evansville, IN-KY Gibson County, IN Posey County, IN Vanderburgh County, IN Warrick County, IN Henderson County, KY Webster County, KY	0.8522
21820	Fairbanks, AK Fairbanks North Star Borough, AK	1.1114
21940	Fajardo, PR Ceiba Municipio, PR Fajardo Municipio, PR Luquillo Municipio, PR	0.3790
22020	Fargo, ND-MN Cass County, ND Clay County, MN	0.8172
22140	Farmington, NM San Juan County, NM	0.7889
22180	Fayetteville, NC Cumberland County, NC Hoke County, NC	0.9358
22220	Fayetteville-Springdale-Rogers, AR-MO Benton County, AR Madison County, AR Washington County, AR McDonald County, MO	0.8775
22380	Flagstaff, AZ Coconino County, AZ	1.2475

CBSA Code	Urban Area (Constituent Counties)	Wage Index
22420	Flint, MI Genesee County, MI	1.1234
22500	Florence, SC Darlington County, SC Florence County, SC	0.8114
22520	Florence-Muscle Shoals, AL Colbert County, AL Lauderdale County, AL	0.7998
22540	Fond du Lac, WI Fond du Lac County, WI	0.9660
22660	Fort Collins-Loveland, CO Larimer County, CO	1.0175
22744	Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL	1.0383
22900	Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Sequoyah County, OK	0.7861
23020	Fort Walton Beach-Crestview-Destin, FL Okaloosa County, FL	0.8758
23060	Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN	0.9012
23104	Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX	0.9499
23420	Fresno, CA Fresno County, CA	1.1267
23460	Gadsden, AL Etowah County, AL	0.8266
23540	Gainesville, FL Alachua County, FL Gilchrist County, FL	0.8978

CBSA Code	Urban Area (Constituent Counties)	Wage Index
23580	Gainesville, GA Hall County, GA	0.9123
23844	Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN	0.9288
24020	Glens Falls, NY Warren County, NY Washington County, NY	0.8456
24140	Goldsboro, NC Wayne County, NC	0.9056
24220	Grand Forks, ND-MN Polk County, MN Grand Forks County, ND	0.7775
24300	Grand Junction, CO Mesa County, CO	0.9721
24340	Grand Rapids-Wyoming, MI Barry County, MI Ionia County, MI Kent County, MI Newaygo County, MI	0.9178
24500	Great Falls, MT Cascade County, MT	0.8354
24540	Greeley, CO Weld County, CO	0.9578
24580	Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI	0.9621
24660	Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC	0.9062
24780	Greenville, NC Greene County, NC Pitt County, NC	0.9401

CBSA Code	Urban Area (Constituent Counties)	Wage Index
24860	Greenville-Mauldin-Easley, SC Greenville County, SC Laurens County, SC Pickens County, SC	0.9980
25020	Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR	0.3537
25060	Gulfport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS	0.8783
25180	Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV	0.8965
25260	Hanford-Corcoran, CA Kings County, CA	1.1010
25420	Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA	0.9286
25500	Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA	0.9025
25540	Hartford-West Hartford-East Hartford, CT Hartford County, CT Middlesex County, CT Tolland County, CT	1.1194
25620	Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS	0.7664
25860	Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC	0.9000

CBSA Code	Urban Area (Constituent Counties)	Wage Index
25980[2]	Hinesville-Fort Stewart, GA Liberty County, GA Long County, GA	0.9028
26100	Holland-Grand Haven, MI Ottawa County, MI	0.8696
26180	Honolulu, HI Honolulu County, HI	1.1662
26300	Hot Springs, AR Garland County, AR	0.9004
26380	Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA	0.7875
26420	Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX	0.9841
26580	Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV	0.9097
26620	Huntsville, AL Limestone County, AL Madison County, AL	0.9064
26820	Idaho Falls, ID Bonneville County, ID Jefferson County, ID	0.9436

CBSA Code	Urban Area (Constituent Counties)	Wage Index
26900	Indianapolis-Carmel, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN	0.9742
26980	Iowa City, IA Johnson County, IA Washington County, IA	0.9548
27060	Ithaca, NY Tompkins County, NY	1.0112
27100	Jackson, MI Jackson County, MI	0.8720
27140	Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS	0.8186
27180	Jackson, TN Chester County, TN Madison County, TN	0.8581
27260	Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL	0.9105
27340	Jacksonville, NC Onslow County, NC	0.8026
27500	Janesville, WI Rock County, WI	0.9201

CBSA Code	Urban Area (Constituent Counties)	Wage Index
27620	Jefferson City, MO Callaway County, MO Cole County, MO Moniteau County, MO Osage County, MO	0.8709
27740	Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN	0.7722
27780	Johnstown, PA Cambria County, PA	0.8233
27860	Jonesboro, AR Craighead County, AR Poinsett County, AR	0.7722
27900	Joplin, MO Jasper County, MO Newton County, MO	0.8285
28020	Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI	1.0264
28100	Kankakee-Bradley, IL Kankakee County, IL	1.0174

CBSA Code	Urban Area (Constituent Counties)	Wage Index
28140	Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO	0.9679
28420	Kennewick-Pasco-Richland, WA Benton County, WA Franklin County, WA	1.0448
28660	Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX	0.8702
28700	Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA	0.7999
28740	Kingston, NY Ulster County, NY	0.9367

CBSA Code	Urban Area (Constituent Counties)	Wage Index
28940	Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN	0.7881
29020	Kokomo, IN Howard County, IN Tipton County, IN	0.9862
29100	La Crosse, WI-MN Houston County, MN La Crosse County, WI	0.9915
29140	Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN	0.9181
29180	Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA	0.8516
29340	Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA	0.7985
29404	Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI	1.0475
29420	Lake Havasu City-Kingman, AZ Mohave County, AZ	1.0567
29460	Lakeland-Winter Haven, FL Polk County, FL	0.8390
29540	Lancaster, PA Lancaster County, PA	0.9204
29620	Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI	0.9770
29700	Laredo, TX Webb County, TX	0.8078

CBSA Code	Urban Area (Constituent Counties)	Wage Index
29740	Las Cruces, NM Dona Ana County, NM	0.8939
29820	Las Vegas-Paradise, NV Clark County, NV	1.2130
29940	Lawrence, KS Douglas County, KS	0.8580
30020	Lawton, OK Comanche County, OK	0.7847
30140	Lebanon, PA Lebanon County, PA	0.8119
30300	Lewiston, ID-WA Nez Perce County, ID Asotin County, WA	0.9570
30340	Lewiston-Auburn, ME Androscoggin County, ME	0.9085
30460	Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY	0.8889
30620	Lima, OH Allen County, OH	0.9379
30700	Lincoln, NE Lancaster County, NE Seward County, NE	0.9563
30780	Little Rock-North Little Rock-Conway, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR	0.8559
30860	Logan, UT-ID Franklin County, ID Cache County, UT	0.8993

CBSA Code	Urban Area (Constituent Counties)	Wage Index
30980	Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX	0.8049
31020	Longview, WA Cowlitz County, WA	1.0707
31084	Los Angeles-Long Beach-Santa Ana, CA Los Angeles County, CA	1.2039
31140	Louisville-Jefferson County, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Jefferson County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY	0.8964
31180	Lubbock, TX Crosby County, TX Lubbock County, TX	0.8751
31340	Lynchburg, VA Amherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA	0.8521
31420	Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA	0.9826

CBSA Code	Urban Area (Constituent Counties)	Wage Index
31460	Madera-Chowchilla, CA Madera County, CA	0.7958
31540	Madison, WI Columbia County, WI Dane County, WI Iowa County, WI	1.1234
31700	Manchester-Nashua, NH Hillsborough County, NH	1.0171
31740	Manhattan, KS Geary County, KS Pottawatomie County, KS Riley County, KS	0.7878
31860	Mankato-North Mankato, MN Blue Earth County, MN Nicollet County, MN	0.9177
31900	Mansfield, OH Richland County, OH	0.9100
32420	Mayagüez, PR Hormigueros Municipio, PR Mayagüez Municipio, PR	0.3704
32580	McAllen-Edinburg-Mission, TX Hidalgo County, TX	0.8852
32780	Medford, OR Jackson County, OR	1.0070
32820	Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN	0.9268
32900	Merced, CA Merced County, CA	1.2123
33124	Miami-Miami Beach-Kendall, FL Miami-Dade County, FL	0.9954

CBSA Code	Urban Area (Constituent Counties)	Wage Index
33140	Michigan City-La Porte, IN LaPorte County, IN	0.9311
33260	Midland, TX Midland County, TX	0.9546
33340	Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI	1.0151
33460	Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI	1.1095
33540	Missoula, MT Missoula County, MT	0.9206
33660	Mobile, AL Mobile County, AL	0.7785
33700	Modesto, CA Stanislaus County, CA	1.2502
33740	Monroe, LA Ouachita Parish, LA Union Parish, LA	0.7752
33780	Monroe, MI Monroe County, MI	0.8885

CBSA Code	Urban Area (Constituent Counties)	Wage Index
33860	Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL	0.8304
34060	Morgantown, WV Monongalia County, WV Preston County, WV	0.8459
34100	Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN	0.7201
34580	Mount Vernon-Anacortes, WA Skagit County, WA	1.0452
34620	Muncie, IN Delaware County, IN	0.8386
34740	Muskegon-Norton Shores, MI Muskegon County, MI	0.9823
34820	Myrtle Beach-North Myrtle Beach-Conway, SC Horry County, SC	0.8730
34900	Napa, CA Napa County, CA	1.4453
34940	Naples-Marco Island, FL Collier County, FL	0.9662
34980	Nashville-Davidson—Murfreesboro-Franklin, TN Cannon County, TN Cheatham County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN	0.9689

CBSA Code	Urban Area (Constituent Counties)	Wage Index
35004	Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY	1.2477
35084	Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA	1.1419
35300	New Haven-Milford, CT New Haven County, CT	1.1545
35380	New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA	0.9092
35644	New York-White Plains-Wayne, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY	1.3005
35660	Niles-Benton Harbor, MI Berrien County, MI	0.8903
35980	Norwich-New London, CT New London County, CT	1.1399

CBSA Code	Urban Area (Constituent Counties)	Wage Index
36084	Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA	1.6404
36100	Ocala, FL Marion County, FL	0.8556
36140	Ocean City, NJ Cape May County, NJ	1.0160
36220	Odessa, TX Ector County, TX	0.9862
36260	Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT	0.9361
36420	Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McClain County, OK Oklahoma County, OK	0.8900
36500	Olympia, WA Thurston County, WA	1.1531
36540	Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sarpy County, NE Saunders County, NE Washington County, NE	0.9608
36740	Orlando-Kissimmee, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL	0.8951
36780	Oshkosh-Neenah, WI	0.9152

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	Winnebago County, WI	
36980	Owensboro, KY Daviess County, KY Hancock County, KY McLean County, KY	0.8357
37100	Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA	1.2301
37340	Palm Bay-Melbourne-Titusville, FL Brevard County, FL	0.9060
37380	Palm Coast, FL Flagler County, FL	0.9603
37460	Panama City-Lynn Haven-Panama City Beach, FL Bay County, FL	0.8324
37620	Parkersburg-Marietta-Vienna, WV-OH Washington County, OH Pleasants County, WV Wirt County, WV Wood County, WV	0.7716
37700	Pascagoula, MS George County, MS Jackson County, MS	0.8433
37764	Peabody, MA Essex County, MA	1.0871
37860	Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL	0.8312
37900	Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL	0.9155
37964	Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA	1.0739

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	Philadelphia County, PA	
38060	Phoenix-Mesa-Scottsdale, AZ Maricopa County, AZ Pinal County, AZ	1.0630
38220	Pine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR	0.7281
38300	Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA	0.8625
38340	Pittsfield, MA Berkshire County, MA	1.0658
38540	Pocatello, ID Bannock County, ID Power County, ID	0.9239
38660	Ponce, PR Juana Díaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR	0.4220
38860	Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME	1.0187

CBSA Code	Urban Area (Constituent Counties)	Wage Index
38900	Portland-Vancouver-Beaverton, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA	1.1498
38940	Port St. Lucie, FL Martin County, FL St. Lucie County, FL	0.9896
39100	Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY	1.1216
39140	Prescott, AZ Yavapai County, AZ	1.0121
39300	Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI	1.0782
39340	Provo-Orem, UT Juab County, UT Utah County, UT	0.9548
39380	Pueblo, CO Pueblo County, CO	0.8570
39460	Punta Gorda, FL Charlotte County, FL	0.8774
39540	Racine, WI Racine County, WI	0.9373
39580	Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC	0.9663

CBSA Code	Urban Area (Constituent Counties)	Wage Index
39660	Rapid City, SD Meade County, SD Pennington County, SD	1.0046
39740	Reading, PA Berks County, PA	0.9263
39820	Redding, CA Shasta County, CA	1.4039
39900	Reno-Sparks, NV Storey County, NV Washoe County, NV	1.0285
40060	Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Chesterfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA	0.9521
40140	Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA	1.1285

CBSA Code	Urban Area (Constituent Counties)	Wage Index
40220	Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA	0.8671
40340	Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN	1.1136
40380	Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY	0.8724
40420	Rockford, IL Boone County, IL Winnebago County, IL	1.0152
40484	Rockingham County-Strafford County, NH Rockingham County, NH Strafford County, NH	1.0125
40580	Rocky Mount, NC Edgecombe County, NC Nash County, NC	0.8845
40660	Rome, GA Floyd County, GA	0.8915
40900	Sacramento--Arden-Arcade--Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA	1.4073
40980	Saginaw-Saginaw Township North, MI Saginaw County, MI	0.9122
41060	St. Cloud, MN Benton County, MN Stearns County, MN	1.1107

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41100	St. George, UT Washington County, UT	0.9236
41140	St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO	1.0189
41180	St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO	0.9102
41420	Salem, OR Marion County, OR Polk County, OR	1.0974
41500	Salinas, CA Monterey County, CA	1.5207
41540	Salisbury, MD Somerset County, MD Wicomico County, MD	0.9110

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41620	Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT	0.9378
41660	San Angelo, TX Irion County, TX Tom Green County, TX	0.7914
41700	San Antonio, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX	0.8857
41740	San Diego-Carlsbad-San Marcos, CA San Diego County, CA	1.1752
41780	Sandusky, OH Erie County, OH	0.8888
41884	San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA	1.5874
41900	San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR	0.4740
41940	San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA	1.6404

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41980	San Juan-Caguas-Guaynabo, PR	0.4363
	Aguas Buenas Municipio, PR	
	Aibonito Municipio, PR	
	Arecibo Municipio, PR	
	Barceloneta Municipio, PR	
	Barranquitas Municipio, PR	
	Bayamón Municipio, PR	
	Caguas Municipio, PR	
	Camuy Municipio, PR	
	Canóvanas Municipio, PR	
	Carolina Municipio, PR	
	Cataño Municipio, PR	
	Cayey Municipio, PR	
	Ciales Municipio, PR	
	Cidra Municipio, PR	
	Comerío Municipio, PR	
	Corozal Municipio, PR	
	Dorado Municipio, PR	
	Florida Municipio, PR	
	Guaynabo Municipio, PR	
	Gurabo Municipio, PR	
	Hatillo Municipio, PR	
	Humacao Municipio, PR	
	Juncos Municipio, PR	
	Las Piedras Municipio, PR	
	Loíza Municipio, PR	
	Manatí Municipio, PR	
	Maunabo Municipio, PR	
	Morovis Municipio, PR	
	Naguabo Municipio, PR	
	Naranjito Municipio, PR	
	Orocovis Municipio, PR	
	Quebradillas Municipio, PR	
	Río Grande Municipio, PR	
	San Juan Municipio, PR	
	San Lorenzo Municipio, PR	
	Toa Alta Municipio, PR	
	Toa Baja Municipio, PR	
	Trujillo Alto Municipio, PR	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR	
42020	San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA	1.2550
42044	Santa Ana-Anaheim-Irvine, CA Orange County, CA	1.1972
42060	Santa Barbara-Santa Maria-Goleta, CA Santa Barbara County, CA	1.2213
42100	Santa Cruz-Watsonville, CA Santa Cruz County, CA	1.6735
42140	Santa Fe, NM Santa Fe County, NM	1.0694
42220	Santa Rosa-Petaluma, CA Sonoma County, CA	1.5891
42340	Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA	0.9043
42540	Scranton--Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA	0.8375
42644	Seattle-Bellevue-Everett, WA King County, WA Snohomish County, WA	1.1577

CBSA Code	Urban Area (Constituent Counties)	Wage Index
42680	Sebastian-Vero Beach, FL Indian River County, FL	0.9362
43100	Sheboygan, WI Sheboygan County, WI	0.9166
43300	Sherman-Denison, TX Grayson County, TX	0.8064
43340	Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA	0.8383
43580	Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD	0.9094
43620	Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD	0.8983
43780	South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI	0.9690
43900	Spartanburg, SC Spartanburg County, SC	0.9341
44060	Spokane, WA Spokane County, WA	1.0444
44100	Springfield, IL Menard County, IL Sangamon County, IL	0.9545
44140	Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA	1.0373

CBSA Code	Urban Area (Constituent Counties)	Wage Index
44180	Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO	0.8453
44220	Springfield, OH Clark County, OH	0.9195
44300	State College, PA Centre County, PA	0.9096
44700	Stockton, CA San Joaquin County, CA	1.2331
44940	Sumter, SC Sumter County, SC	0.8152
45060	Syracuse, NY Madison County, NY Onondaga County, NY Oswego County, NY	0.9785
45104	Tacoma, WA Pierce County, WA	1.1195
45220	Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL Wakulla County, FL	0.8406
45300	Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL	0.8982
45460	Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN	0.9061
45500	Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX	0.8113

CBSA Code	Urban Area (Constituent Counties)	Wage Index
45780	Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH	0.9541
45820	Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS	0.9026
45940	Trenton-Ewing, NJ Mercer County, NJ	1.0552
46060	Tucson, AZ Pima County, AZ	0.9505
46140	Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK	0.8662
46220	Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL	0.8698
46340	Tyler, TX Smith County, TX	0.8312
46540	Utica-Rome, NY Herkimer County, NY Oneida County, NY	0.8460
46660	Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA	0.7944
46700	Vallejo-Fairfield, CA	1.4934

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	Solano County, CA	
47020	Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX	0.8054
47220	Vineland-Millville-Bridgeton, NJ Cumberland County, NJ	1.0207
47260	Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surry County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA	0.8960
47300	Visalia-Porterville, CA Tulare County, CA	1.0221
47380	Waco, TX McLennan County, TX	0.8377
47580	Warner Robins, GA Houston County, GA	0.8754
47644	Warren-Troy-Farmington Hills, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI	0.9806

CBSA Code	Urban Area (Constituent Counties)	Wage Index
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV	1.0882
47940	Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA	0.8518
48140	Wausau, WI Marathon County, WI	0.9440
48260	Weirton-Steubenville, WV-OH Jefferson County, OH Brooke County, WV Hancock County, WV	0.7368
48300	Wenatchee-East Wenatchee, WA Chelan County, WA Douglas County, WA	0.9719
48424	West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL	0.9879

CBSA Code	Urban Area (Constituent Counties)	Wage Index
48540	Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV	0.6869
48620	Wichita, KS Butler County, KS Harvey County, KS Sedgwick County, KS Sumner County, KS	0.9018
48660	Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX	0.9197
48700	Williamsport, PA Lycoming County, PA	0.7877
48864	Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ	1.0555
48900	Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC	0.8986
49020	Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV	0.9777
49180	Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC	0.8953
49340	Worcester, MA Worcester County, MA	1.1089
49420	Yakima, WA Yakima County, WA	0.9949

CBSA Code	Urban Area (Constituent Counties)	Wage Index
49500	Yauco, PR Guánica Municipio, PR Guayanilla Municipio, PR Peñuelas Municipio, PR Yauco Municipio, PR	0.3348
49620	York-Hanover, PA York County, PA	0.9299
49660	Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA	0.8679
49700	Yuba City, CA Sutter County, CA Yuba County, CA	1.1265
49740	Yuma, AZ Yuma County, AZ	0.9143

[2]At this time, there are no hospitals in these urban areas on which to base a wage index. Therefore, the urban wage index value is based on the average wage index of all urban areas within the State.

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