DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
[CMS–1555–N]
RIN 0938–AP20
Medicare Program: Home Health Prospective Payment System Rate Update for Calendar Year 2009
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Notice.
SUMMARY: This notice sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health services, effective on January 1, 2009.
DATES: Effective Date: This notice is effective on January 1, 2009.
FOR FURTHER INFORMATION CONTACT: Randy Thordset, (410) 786–0131.
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 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 PP as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41124).
B. Deficit Reduction Act of 2005
On February 8, 2006, the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) was enacted. This legislation affected updates to HH payment rates for calendar year (CY) 2006. The DRA also required HHAs to submit home health care quality data and created a linkage between those data and payment, beginning in CY 2007.
Specifically, section 5201 of the DRA changed the CY 2006 update from the applicable home health market basket percentage increase minus 0.8 percentage points to a 0 percent update. In addition, section 5201 of the DRA amended section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003). The amended section 421(a) of the MMA requires that for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) on or after January 1, 2006 and before January 1, 2007, the Secretary increase the payment amount otherwise made under section 1895 of the Act for home health services by 5 percent. The statute waives budget neutrality for purposes of this increase since it specifically states that the Secretary must not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to home health services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.
The 0 percent update to the payment rates and the rural add-on provisions of the DRA were implemented through a CMS transmittal (Pub. 100–20, One Time Notification, Transmittal 211) issued on February 10, 2006.
In addition, 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). In addition, the November 2006 final rule ended the 1-year transition period that consisted of a blend of 50 percent of the new area labor market designations’ wage index and 50 percent of the previous area labor market designations’ wage index. We also revised the fixed dollar loss ratio, which is used in the calculation of outlier payments.

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 payment rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) and non-routine medical supplies. Durable medical equipment covered under home health 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 amount by discipline; an episode consisting of four or fewer visits within a 60-day period is referred to as a LUPA. Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial payment rate for certain intervening events: Higher resource use per episode and a different relationship between clinical conditions and resource use. We use additional variables to include scores for certain wound and skin conditions; more diagnosis groups such as pulmonary, cardiac, and cancer diagnoses; and certain secondary diagnoses. The 4-equation model results in 153 case-mix groups. In addition, we replaced the previous single therapy threshold of 10 visits with three therapy thresholds at 6, 14, and 20 visits. The payment for additional therapy visits between the three thresholds increases gradually, incorporating a declining, rather than a constant, amount per added therapy visit. This approach does not reduce total payments to home health providers because the payment model still predicts total resource cost. The combined effect of the new therapy thresholds and payment gradations reduces the undesirable emphasis in treatment planning on a single therapy visit threshold and restores the primacy of clinical considerations in treatment planning for rehabilitation patients.

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The CY 2008 HH PPS final rule with comment period also implemented refinements to the payment system. Extensive research was conducted to investigate ways to improve the performance of the case-mix model. This research was the basis for our decision to refine the case-mix model. We refined the case-mix model to reflect different resource costs for early home health episodes versus later home health episodes and to expand the case-mix variables included in the payment model. For 2008, we used a 4-equation case-mix model that recognizes and differentiates payment for episodes of care based on whether a patient is in an early (1st or 2nd episode in a sequence of adjacent episodes) or later (the 3rd episode and beyond in a sequence of adjacent episodes) episode of care as well as recognizing whether a patient was a high therapy (14 or more therapy visits) or low therapy (13 or fewer therapy visits) case. We defined episodes as adjacent if they were separated by no more than a 60-day period between claims. Analysis of the performance of the case-mix model for later episodes revealed two important differences for episodes occurring later in the home health treatment compared to earlier episodes: Higher resource use per episode and a different relationship between clinical conditions and resource use. We use additional variables to include scores for certain wound and skin conditions; more diagnosis groups such as pulmonary, cardiac, and cancer diagnoses; and certain secondary diagnoses. The 4-equation model results in 153 case-mix groups.

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The CY 2008 HH PPS final rule with comment period, we further adjusted for case-mix that was not due to a change in the underlying health status of the home health users. Section 1895(b)(3)(B) of the Act requires that in compensating for case-mix change, a payment reduction must be applied to the standardized payment amount. For the CY 2008 HH PPS final rule with comment period, we conducted several analyses to determine if any portion of the total change in case-mix could be considered to be real change. Real change is a change in the underlying health status of the home health user population. The results of the analysis indicated that while a small amount (8.03 percent) of measured case-mix change was real, most of the change was unrelated to the underlying health status of home health users.

Using 100 percent of the home health interim payment system (HH IPS) file for our baseline (12 months ending September 30, 2000), the average case-mix weight per episode was 1.0960. (The HH IPS was the previous cost-based payment system under which HHAs were paid, prior to the HH PPS.) The 2005 20 percent sample file yielded an average CMI (case mix indicator) of 1.2361. Therefore, the change measurement was (1.2361 − 1.0960)/1.0960 = 0.1278 percent. We adjusted this result downward by 8.03 percent (the percentage of total change in case-mix considered to be real) to get a final case-mix change measure of 11.75 percent (0.1278 * (1 − 0.0803) = 0.1175). To account for the 11.75 percent increase in case-mix which was not due to a change in the underlying health status of Medicare home health patients, we implemented a 2.75 percent reduction of the national standardized 60-day episode payment rate for 3 years beginning in 2008 and solicited comments on extending that adjustment period to a fourth year based on a 2.71 percent reduction for 2011 (see 72 FR 49833).

Additionally, we modified a number of existing HH PPS payment adjustments. Specifically, we increased the payment for low utilization payment adjustment (LUPA) episodes that occur as the only episode or the initial episode during a sequence of adjacent episodes, by $87.93. We also eliminated the significant change in condition (SCIC)
payment adjustment for various reasons. Specifically, we ended the policy because of the apparent difficulty HHAs had in interpreting the SCIC policy, the association between negative margins and SCIC episodes, the decline in the occurrence of SCICs, and the estimated minimal impact on outlays from eliminating the SCIC policy.

In the development of the HH PPS, non-routine medical supplies (NRS) were accounted for by attributing $49.62 to the standardized episode payment. In the CY 2008 HH PPS final rule with comment period, we applied a severity adjustment to the NRS portion of the HH PPS standardized episode payment. Specifically, we adopted a six-severity-group approach to account for NRS costs (see 72 FR 49851–49852) based on measurable conditions that are feasible to administer. This change offers HHAs some protection against episodes with extremely high NRS costs. Finally, we did not modify the existing Partial Episode Payment (PEP) Adjustment. Section 1895(b)(5) of the Act also allows for the provision of an addition or adjustment to account for outlier episodes, which are those episodes that incur unusually large costs due to heavy patient care needs. 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 episode becomes eligible for outlier payments. Section 1895(b)(5) of the Act requires that the estimated total outlier payments may not exceed 5 percent of total estimated HH PPS payments. In the CY 2008 HH PPS final rule with comment period, we adjusted the FDL ratio to 0.89, based on the most recently available data, analysis, trends, and unknown effects of the refinements on outliers (see 72 FR 49857).

Finally, we expanded the list of quality measures identified in the update notice for CY 2007. In CY 2007, we specified 10 OASIS quality measures from the OASIS data set as appropriate for public reporting and measurement of health care quality. For CY 2008, we added two more quality measures from the OASIS data set for public reporting. All twelve publicly reported measures are National Quality Forum (NQF)-endorsed measures. The additional measures for 2008 were as follows:

- Emergent Care for Wound Infection, Deteriorating Wound Status; and
- Improvement in the Status of Surgical Wounds (see 72 FR 49861).

Accordingly, for CY 2008, we considered the existing OASIS data set submitted by HHAs to CMS for episodes beginning on or after July 1, 2006, and before July 1, 2007, as meeting the reporting requirement for quality measures for CY 2008.

II. Comments Received From CY 2008 HH PPS Final Rule With Comment Period

In the CY 2008 HH PPS final rule with comment period, we implemented a 2.75 percent payment reduction of the national standardized 60-day episode payment rate for three years beginning in CY 2008 and a fourth year reduction of 2.71 percent for CY 2011. We sought comments only on the 2.71 percent case-mix change adjustment for 2011. We received approximately 44 items of correspondence from the public, only a few of which were directly related to the 2.71 percent adjustment to the HH PPS 60-day episode payment rate in the fourth year. The provision for the 2.71 percent adjustment was added as the fourth year’s reduction to the rates to account for the additional change in case-mix, that was indicated in the analysis for the CY 2008 final rule with comment period, that is not considered real; i.e., that is not related to an underlying change in patient health status. Comments originated from trade associations, HHAs, hospitals, and health care professionals such as physicians, nurses, social workers, and physical and occupational therapists. Because this is an update notice, we are not changing policy. However, in order to provide more meaningful and substantive responses we will respond to the above mentioned comments in future rulemaking. This approach allows us to respond comprehensively as more current data become available, while also affording the public ample opportunity to comment on possible future policy changes.

At this time, CMS is maintaining our existing policy as implemented in the CY 2008 final rule with comment period and will impose a 2.75 percent reduction to the national standardized 60-day episode rate for CY 2009. We will continue to monitor any changes in case-mix and may revise the percentage reductions to the HH PPS rates in future rulemaking.

III. Provisions of This Notice

A. National Standardized 60-Day Episode Rate

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the final rule published July 3, 2000 in the Federal Register (65 FR 41128), the unit of payment under the Medicare HH PPS is a national standardized 60-day episode rate. As set forth in § 484.220, we adjust the national standardized 60-day episode rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. In the CY 2008 HH PPS final rule with comment period, we refined the case-mix methodology and also rebased and revised the home health market basket. The labor-related share of the case-mixed adjusted 60-day episode rate is 77.082 percent and the non-labor-related share is 22.918 percent. The CY 2009 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.

In accordance with section 1895(b)(3)(B) of the Act, we have updated the HH PPS rates annually in a separate Federal Register document. The HH PPS regulations at § 484.225 sets forth the specific annual percentage update. To reflect section 1895(b)(3)(B)(v) of the Act, as added by section 5201 of the DRA, we added § 484.225, paragraphs (b) and (i), in the November 9, 2006 final rule to reflect the requirement for submission of quality data, as follows:

(b) For 2007 and subsequent calendar years, in the case of a home health agency that submits home health quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount.

(i) For 2007 and subsequent calendar years, in the case of a home health agency that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount.
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 “low utilization payment adjustment” (LUPA). We update the national per-visit amounts by discipline annually by the applicable home health market basket percentage. We adjust the national per-visit amount 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 amounts by discipline used to calculate the LUPA 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 are also updating the amounts of the LUPA add-on and the NRS conversion factor by the applicable home health market basket update of 2.9 percent for CY 2009.

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. CY 2009 Update to the Home Health Market Basket Index

Section 1895(b)(3)(B) of the Act, as amended by section 5201 of the DRA, requires for CY 2009 that the standard prospective payment amounts be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary.

The applicable home health market basket update will be reduced by 2 percentage points for those HHAs that fail to submit the required quality data. This requirement has been codified in regulations at 42 CFR 484.225. The HH PPS market basket update for CY 2009 is 2.9 percent. This is based on Global Insights Inc.’s, third quarter 2008 forecast, utilizing historical data through the second quarter of 2008. A detailed description of how we derived the HHA market basket is available in the CY 2008 Home Health PPS proposed rule (72 FR 25356, 25435).

- CY 2009 Adjustments

In order to calculate the CY 2009 national standardized 60-day episode rate, we first increase the CY 2008 national standardized 60-day episode payment rate of $2,270.32 by the home health market basket update of 2.9% for CY 2009.

Given this updated rate, we then take a reduction of 2.75 percent to account for the change in case-mix that is not related to the real change in patient acuity levels, as discussed above. The resulting updated CY 2009 national standardized 60-day episode rate for an HHA that submits the required quality data is shown in Table 1. The updated CY 2009 national standardized 60-day episode rate for an HHA that does not submit the required quality data is shown in Table 2.

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<th>TABLE 1—NATIONAL 60-DAY EPISODE AMOUNTS UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2009, BEFORE CASE-MIX ADJUSTMENT, WAGE INDEX ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY</th>
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1 The estimated home health market basket update of 2.9 percent for CY 2009 is based on Global Insight Inc., 3rd Qtr 2008 forecast with historical data through 2nd Qtr 2008.

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<th>TABLE 2—FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA—NATIONAL 60-DAY EPISODE AMOUNTS UPDATED BY THE HOME HEALTH MARKET BASKET UPDATE FOR CY 2009, BEFORE CASE-MIX ADJUSTMENT, WAGE INDEX ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY</th>
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1 The estimated home health market basket update of 2.9 percent for CY 2009 is based on Global Insight Inc., 3rd Qtr 2008 forecast with historical data through 2nd Qtr 2008.
Payment for LUPA episodes changed in CY 2008 in that for LUPAs that occur as initial episodes in a sequence of adjacent episodes or as the only episode, an additional payment amount is added to the LUPA payment. The Table 3 per-visit rates noted above are before that additional payment is added to the LUPA payment, and are the per-visit rates paid to all other LUPA episodes and used in computing outlier payments. LUPA episodes that occur as the only episode or initial episode in a sequence of adjacent episodes are adjusted by adding an additional amount to the LUPA payment before adjusting for wage index. For CY 2008, that amount was $87.93. This additional LUPA amount is updated in the same manner as the national standardized 60-day episode payment amount and the per-visit rates (i.e., by the home health market basket percentage update). Consequently, for CY 2009, the additional amount paid to LUPAs that occur as initial episodes in a sequence of adjacent episodes or as the only episode is 90.48 ($87.93 × 1.029).

Beginning in CY 2008, to ensure that the variation in non-routine medical supplies (NRS) is more appropriately reflected in the HH PPS, we replaced the original portion ($49.62) of the HH PPS base rate that accounted for NRS, with a system that pays for NRS based on 6 severity groups. For a complete description of the analysis and research behind the development of this system for the payment of NRS, we refer readers to the CY 2008 HH PPS proposed rule (72 FR 25426–25434). Following public comment on the initial proposal made in the proposed rule, we made several modifications using a file of more recent data. The revisions resulted in some scoring changes, and the addition of the sixth severity group to the original five severity groups, to provide more adequate reimbursement for episodes with a high utilization of NRS. As we did in the CY 2008 HH PPS final rule with comment, payments for NRS are updated by the home health market basket and reduced by the 2.75 percent reduction to the rates through the updating of the NRS conversion factor. NRS payments are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. For this notice, the NRS conversion factor is updated by the home health market basket update of 2.9 percent and reduced by the 2.75 percent reduction to the rates. The NRS conversion factor for CY 2008 was $52.35. Consequently, for CY 2009, the NRS conversion factor is $52.39 (52.35 × (1.029 × (1 − 0.0275))). The payment amounts for the various severity levels based on the updated conversion factor are calculated in Table 4.
G. Home Health Care Quality Improvement

Section 5201(c)(2) of the DRA added section 1895(b)(3)(B)(v)(II) to the Act, requiring that, starting with the initial reporting year from July 2005 through June 2006 and each year thereafter, "each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality." In response to the DRA requirements, CMS published information about the quality measures in the Federal Register as a proposed rule on August 3, 2006 (71 FR 44082–44090) and as a final rule on November 9, 2006 (71 FR 65903). We proposed, and made final, the decision to use the subset of OASIS data that is publicly reported on Home Health Compare, as the appropriate measures of home health quality.

Therefore, OASIS assessments submitted by HHAs to CMS in compliance with HHA conditions of participation for dates of service beginning July 1, 2007 and ending June 30, 2008 will fulfill the HH PPS quality reporting requirement for CY 2009 payments. This reporting time period allows for 12 full months of data and provides us the time necessary to analyze and make any necessary payment adjustments to the CY 2009 payment rates. The required quality measures for meeting the submission requirements for CY 2009 are the same as those required for meeting the submission requirements for CY 2008. These measures are:

- Improvement in Ambulation/ Locomotion,
- Improvement in Bathing,
- Improvement in Transferring,
- Improvement in Management of Oral Medication,
- Improvement in Pain Interfering with Activity,
- Acute Care Hospitalization,
- Emergent Care,
- Discharge to Community,
- Improvement in Dyspnea,
- Improvement in Urinary incontinence,
- Improvement in surgical wounds, and
- Emergent Care for wound deterioration.

HHAs that meet the reporting requirements are eligible for the full home health market basket percentage increase. Consistent with our previous policy, home health agencies that are certified on or after May 1, 2007 for payments to be made in CY 2009 will be excluded from the quality reporting requirement in CY 2009 because data submission and analysis will not be possible for an agency certified this late in the reporting time period. At the earliest time possible after obtaining the CCN number, reporting is mandatory. These exclusions only affect quality reporting requirements and do not affect the agency’s OASIS reporting responsibilities under the CoP submission requirement.

Additionally, section 1895(b)(3)(B)(v)(II) of the Act requires that all HHAs, unless covered by specific exclusions, meet the reporting requirement, or be subject to a 2 percent reduction in the home health market basket percentage increase. CMS will reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements on an annual cycle July 1 through June 30. The 2 percent reduction applies to all HHAs who have not submitted an OASIS assessment in the required time frame for payments beginning in January 2007 and each year thereafter. We will reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements. Section 1895(b)(3)(B)(v)(III) of the Act further requires that "[t]he Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public." To meet the requirement for making such data public, we will continue to use the Home Health Compare Web site, which lists HHAs geographically. Currently, the Home Health Compare Web site lists 12 quality measures from the OASIS set, and these 12 measures are all NQF-endorsed measures for public reporting. Consumers can search for all Medicare-approved home health providers that serve their city or zip code (which would include the quality measures) and then find the agencies offering the types of services they need. See http://www.medicare.gov/HHCompare/Home.asp. HHAs currently have pre-publication access every November to their own agency’s quality data (collected and periodically updated by a contractor), which enables each agency to know how it is performing before public posting of data on the Home Health Compare Web site. In addition, each agency formally receives quarterly updates via the CASPER system known as Outcome and Quality Improvement (OBQI) and Outcome Based Quality Monitoring (OBQM) and a report describing the agency patient characteristics based on OASIS. Continuing to use the OASIS instrument ensures that providers will not have an additional burden of reporting through a separate mechanism and that the costs associated with the development and testing of a new reporting mechanism can be avoided. For CY 2009, we will continue to require that the HHA submit OASIS data appropriate for the measurement of health care quality.

Over the past year, CMS has tested new patient level best practice and process measures for home health agencies, and has continued to refine the current OASIS instrument. CMS is testing the new measure the NQF has developed a Global Measure for Flu/Pneumonia vaccination across care settings. We anticipate making further modifications to the current OASIS items, including refinements to response categories. Any new data elements go through OMB process and measures go through the NQF consensus development process, prior to proposing them through the rulemaking process. Additionally, section 1895(b)(3)(B)(v)(II) of the Act requires each HHA to submit appropriate health care quality data in a form, manner, and at a time specified by the Secretary. Such measures would be evidence-based, clearly linked to improved outcomes, and reliably captured with the least burden to the provider. Data element revisions and measures across settings of care will be integral to CMS’ vision of addressing national quality care priorities and use of a future single instrument for quality, payment, clinical relevance, and risk adjustment.

D. Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care

As part of the U.S. Department of Health and Human Services (DHHS) Transparency Initiative, CMS plans 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 CAHPS Home Health Care survey is part of a family of CAHPS® surveys that ask patients to report on and rate their experiences with health care. This notice provides an update on the development of the CAHPS Home Health Care survey, as initially discussed in the May 4, 2007 proposed rule (72 FR 25356, 25452). The CAHPS® Home Health Care survey presents home health patients with a set of standardized questions about their
E. Outliers and the Fixed Dollar Loss Ratio

In addition to the regular 60-day case-mix and wage-adjusted episode payments, the HH PPS allows for outlier payments for episodes that incur unusually high costs. As noted in section I.A., of this notice, outlier payments are made for episodes for which the estimated cost exceeds a threshold amount. Section 1895(b)(5) of the Act requires that the estimated total outlier payments be no more than 5 percent of total estimated HH PPS payments for a given year. For a full description of our outlier policy, we refer to the CY 2008 HH PPS final rule with comment period (72 FR 49855–49857).

The wage adjusted fixed dollar loss (FDL) amount represents the amount of loss that an agency must bear before an episode becomes eligible for outlier payments. Annually, we review the percentage of outlier payments and adjust the FDL ratio as appropriate. Past experience has shown that outlier payments have been increasing as a percent of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007. More recent analysis estimates outlier payments to increase to approximately 8.1 percent in CY 2008 (an increase of slightly more than 27 percent).

In the CY 2008 final rule with comment period, in the interest of using the latest data and best analysis available, we performed supplemental analysis on the most recent FDL ratio in CY 2008. That analysis derived a final FDL ratio of 0.89 for CY 2008.

In order to determine the appropriate value for the FDL ratio for CY 2009 we performed an updated analysis using the most recent, complete available data (CY 2007), applying a methodology similar to that which we used to update the FDL ratio in the CY 2008 HH PPS final rule with comment. That updated analysis projects that in CY 2009 we will expend an estimated 10.26 percent of total estimated HH PPS payments in outlier payments, more than double our 5 percent statutory limit. However, our analysis also revealed that this growth in outlier payments is primarily the result of excessive growth in a few specific areas of the country.

Specifically, we have noticed statistical anomalies in outlier payments, as a percentage of total HH PPS payments, in areas such as Miami-Dade, Florida, where outlier payments to providers far exceed the national average and the 5 percent target for outlier payments. Using similar analysis to what was performed for the CY 2009 final rule with comment; we estimated that we would need to raise our FDL ratio from 0.89 to 2.71 for CY 2009. This is a dramatic change that appears to be driven by statistical anomalies in outlier payments in areas such as Miami-Dade, Florida. In addition, the size of these statistical anomalies raises concerns about the medical necessity of the outlier episodes in some areas. We will be examining outlier payments in these areas in more detail and will take action to remedy inappropriate outlier payments as necessary.

Therefore, we believe that raising the FDL ratio to 2.71 is not justified at this time, given the statistical outlier data anomalies that we have identified in certain areas, and the actions that are underway to address excessive, suspect outlier payments that are occurring in these areas. We believe the most reasonable policy to achieve paying no more than 5 percent outlier payments as a percentage of total estimated HH PPS payments is through the combined effects of maintaining the current (CY 2008) FDL ratio of 0.89 in CY 2009 and the actions being taken to remedy any inappropriate outlier payments in these areas of the country where outlier data anomalies exist. Any further update to the FDL ratio, if any, will not occur until future rulemaking when we expect to have a better understanding of appropriate outlier payments, particularly in those areas of the country with extremely high outlier payments as a percentage of total HH PPS payments.

F. Hospital Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to establish area wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services and to provide appropriate adjustments to the episode payment amounts under the HH PPS to account for area wage differences. As discussed previously, 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).

Generally, we determine each HHA’s labor market area based on definitions of Metropolitan Statistical Areas (MSAs) issued by the Office of Management and Budget (OMB). We have consistently used the pre-floor, pre-reclassified hospital wage index data to adjust the labor portion of the HH PPS rates. We believe the use of the pre-floor, pre-reclassified hospital wage index data results in the appropriate adjustment to
the labor portion of the costs as required by statute.

In the November 9, 2005 final rule for CY 2006 (70 FR 68132), we adopted revised labor market area definitions based on Core-Based Statistical Areas (CBSAs). At the time, we noted that these were the same labor market area definitions (based on OMB’s new CBSA designations) implemented under the Hospital Inpatient Prospective Payment System (IPPS). In adopting the CBSA designations, we identified some geographic areas where there are no IPPS hospitals and, thus, no hospital wage data on which to base the calculation of the home health wage index. We continue to use the methodology discussed in the November 9, 2006 final rule for CY 2007 (71 FR 65884) to address the geographic areas that lack hospital wage data on which to base the calculation of their home health wage index. For rural areas that do not have IPPS hospitals, we use the average wage index from all contiguous CBSAs as a reasonable proxy. This methodology is used to calculate the wage index for rural Massachusetts. However, we could not apply this methodology to rural Puerto Rico due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005). For urban areas without IPPS hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. The only urban area without IPPS hospital wage data is Hispiscule-Fort Stewart, Georgia (CBSA 25090).

1. Clarification of New England Deemed Counties

We are taking this opportunity to address the change in the treatment of “New England deemed counties” (that is, those counties in New England listed at 42 CFR 412.64(b)(1)(ii)(B) that were deemed to be part of urban areas under section 601(g) of the Social Security Amendments of 1983) that was made in the FY 2008 IPPS final rule with comment period (72 FR 457337 through 47338, August 22, 2007). These counties include the following: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Of these five “New England deemed counties,” three (York County, ME; Sagadahoc County, ME; and Newport County, RI) are also included in metropolitan statistical areas defined by OMB that are considered urban under both the current IPPS and HH PPS labor market area definitions in §412.64(b)(1)(ii)(A). The remaining two, Litchfield County, CT, and Merrimack County, NH, are geographically located in areas that are considered rural under the current IPPS (and HH PPS) labor market area definitions, but have been previously deemed urban under the IPPS in certain circumstances, as discussed below.

In the FY 2008 IPPS final rule with comment period, §412.64(b)(1)(ii)(B) was revised such that the two “New England deemed counties” that are still considered rural under the OMB definitions (Litchfield County, CT and Merrimack County, NH), are no longer considered urban effective for discharges occurring on or after October 1, 2007, and therefore, are considered rural in accordance with §412.64(b)(1)(ii)(C). However, for purposes of payment under the IPPS, acute-care hospitals located within those areas are treated as being reclassified to their deemed urban area effective for discharges occurring on or after October 1, 2007 (see 72 FR 47337 through 47338). We note that the HH PPS does not provide for such geographic reclassification. Also, in the FY 2008 IPPS final rule with comment period (72 FR 47338), we explained that we have limited this policy change for the “New England deemed counties” only to IPPS hospitals, and any change to non-IPPS provider wage indexes would be addressed in the respective payment system rules. Accordingly, we are taking this opportunity to clarify the treatment of “New England deemed counties” under the HH PPS in this notice.

As discussed above, the HH PPS has consistently used the IPPS definition of “urban” and “rural” with regard to the wage index used in the HH PPS. Historical changes to the labor market area/geographic classifications and annual updates to the wage index values under the HH PPS are made effective January 1 each year. When we established the most recent HH PPS payment rate update, effective for HH services provided on or after January 1, 2008 through December 31, 2008, we considered the “New England deemed counties” (including Litchfield County, CT and Merrimack County, NH) as urban for CY 2008, as evidenced by the inclusion of Litchfield County as one of the constituent counties of urban CBSA 25540 (Hartford-West Hartford-East Hartford, CT), and the inclusion of Merrimack County as one of the constituent counties of urban CBSA 31700 (Manchester-Nashua, NH). At 42 FR 484.202, the terms “rural” and “urban” are defined according to the definitions of those terms as used in the IPPS. Applying the IPPS definitions, Litchfield County, CT and Merrimack County, NH are not considered “urban” under §412.64(b)(1)(ii)(A) through (B) as revised under the FY 2008 IPPS final rule and, therefore, are considered “rural” under §412.64(b)(1)(ii)(C). Accordingly, reflecting our policy to use the IPPS definitions of “urban” and “rural,” these two counties will be considered “rural” under the HH PPS effective with the next update of the HH PPS payment rates on January 1, 2009, and will no longer be included in urban CBSA 25540 (Hartford-West Hartford-East Hartford, CT) and urban CBSA 31700 (Manchester-Nashua, NH), respectively. We note that this policy is consistent with our policy of not taking into account IPPS geographic reclassifications in determining payments under the HH PPS.

2. Multi-Campus Hospital Wage Index Data

In the CY 2008 HH PPS final rule with comment period, we established HH PPS wage index values for CY 2008 calculated from the same data (collected from cost reports submitted by hospitals for cost reporting periods beginning during FY 2004) used to compute the FY 2008 acute care hospital inpatient wage index, without taking into account geographic reclassification under sections 1886(d)(b) and (d)(10) of the Act. However, the IPPS policy that apportions the wage data for multi-campus hospitals was not finalized before the HH PPS final rule with comment period.

We are continuing to use IPPS wage data for this CY 2009 update notice because we believe that in the absence of home health-specific wage data, using the hospital inpatient wage data is appropriate and reasonable for the HH PPS. We note that the IPPS wage data used to determine the CY 2009 HH wage index values reflect our policy that was adopted under the IPPS beginning in FY 2008, which apportions the wage data for multi-campus hospitals located in different labor market areas, or Core-Based Statistical Areas (CBSAs), to each CBSA where the campuses are located (see the FY 2008 IPPS final rule with comment period (72 FR 47317 through 47320)). Specifically, for the CY 2009 HH PPS, the wage index was computed using IPPS wage data (published by hospitals for cost reporting periods beginning in 2005, as with the FY 2009 IPPS wage index), which allocated salaries and hours to the campuses of two multi-campus hospitals with campuses that are located in different labor areas; one is Massachusetts and the other is Illinois. The wage index...
values for the CY 2009 HH PPS in the following CBSAs are affected by this policy: Boston-Quincy, MA (CBSA 14484), Providence-New Bedford-Falls River, RI-MA (CBSA 39300), Chicago-Naperville-Joliet, IL (CBSA 16974) and Lake County-Kenosha County, IL-WI (CBSA 29404) (please refer to Addendum B in this notice).

As previously discussed in the July 3, 2000 final rule (65 FR 41128), the statute provides that the wage adjustment factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(F) of the Act for hospital wage adjustment factors. Since publication of the July 3, 2000 final rule, we continue to believe that the use of the pre-floor and pre-reclassified hospital wage index data results in the appropriate and reasonable adjustment to the labor portion of the costs as required by statute. 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. See Addenda A and B of this notice, respectively, for the rural and urban pre-floor, pre-reclassified hospital wage indexes for 2009. The 2009 wage index is based on data collected from hospital cost reports submitted for cost reporting periods beginning during FY 2005. These data reflect the multi-campus and New England deemed counties policies discussed above.

Under the HHH PPS, we use the wage index value associated with the labor market in which the beneficiary’s home is located. As has been our longstanding practice, any area not included in an MSA (urban area) is considered to be nonurban (§ 412.64(b)(1)(ii)(C)) and the MSAs (urban area) is considered to be nonurban (§ 412.64(b)(1)(ii)(C)) and receives the statewide rural wage index value (see, for example, 65 FR 41173).

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a notice such as this take effect. We can waive this procedure, however, if we find good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of finding and its reasons in the notice issued.

We find that it is unnecessary, impracticable and contrary to the public interest to undertake proposed notice and comment rulemaking in this Notice. We believe it is unnecessary because the statistical annual updates to the HH PPS rates and the methodologies used to update the rates have been previously subject to public comment; we are simply applying the methodology to the most recent data. With respect to the update of the outlier FDL ratio, we find that insofar as we have deviated from our usual methodology in this calendar year, such change is an analytical change. Moreover, we believe that the difficulty of deriving a new methodology to address the limited data discrepancies in localized areas of the country makes issuing a notice of proposed rulemaking in this instance impracticable.

Moreover, it would be contrary to the public interest to undertake notice and comment rulemaking as it would impose a hardship on home health agencies and their patients by delaying publication of this update in order to solicit comments. Since it would pose additional harm to those home health agencies across the country that would be deemed ineligible for outlier payments because of these localized data discrepancies, applying the FDL analysis that we have used in past years is likewise contrary to the public interest for CY 2009. Therefore, we find good cause to waive notice and comment procedures for CY 2009.

V. Collection of Information

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 501 et seq.).

VI. Regulatory Impact Analysis

A. Overall Impact

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

Executive Order 12866, as amended, which merely reassigns responsibility of duties 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. To the extent feasible, a cost-

The RFA requires agencies to analyze options for regulatory relief 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 purposes of the RFA, approximately 75 percent of HHAs are considered small businesses according to the Small Business Administration’s size standards with total revenues of $13.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. As stated above, this notice will have an estimated positive effect upon small entities that are HHAs (see Section IV.B “Anticipated Effects”, of this 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 603 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. We have determined that this notice 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 that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million adjusted for inflation. Using the Gross Domestic Price Deflator, the inflation adjusted threshold for 2008 is approximately $130 million. We believe this notice will not mandate expenditures in that amount.

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

B. Anticipated Effects

This notice updates the HH PPS rates contained in the CY 2008 HH PPS final rule with comment period. We use the latest data and best analysis available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as days or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based on the latest available Medicare claims from 2006. 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 forecasting errors due to other changes in the forecasted impact time period. 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, 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 5 represents how home health agencies are likely to be affected by the policy changes described in this notice. 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 four simulations and compared them to each other. Based on our estimate that outliers, as a percentage of total HH PPS payments, will be at least 5 percent in CY 2008, the 2008 baseline, for the purposes of these simulations, we assumed that the full 5 percent outlay for outliers will be paid. The first simulation estimates CY 2008 payments under the current system (to include the 2008 wage index and 2008 payment rates). The second simulation estimates CY 2008 payments under the current system, but with the CY 2009 wage index. The second simulation produces an estimate of the effect of the CY 2009 wage index only. The third simulation estimates the effect of the CY 2009 payments using the CY 2009 wage index. The fourth simulation estimates CY 2009 payments using the new CY 2009 payment rates and CY 2009 wage index.

These four simulations allow us to demonstrate the effects of the new CY 2009 wage index and a new CY 2009 payment rates as a percentage change in estimated expenditures. Specifically, the second column of Table 5 shows the percent change due to the effects of the CY 2009 wage index. The third column of Table 5 shows the percent change due to the combined effects of the CY 2009 wage index and the CY 2009 home health market basket update and the case-mix reduction.

Column three shows the percentage change in estimated total payments in moving from the current CY 2008 to the revised CY 2009 system outlined in this notice. Our estimate of the change in total payments between CY 2008 and CY 2009 is an increase of approximately 0.15 percent.

In general, most HHAs are estimated to see increases in total payments from CY 2008 to CY 2009. The increases range from −0.01 percent for other voluntary/non-profit freestanding agencies to 0.25 percent for facility-based governmental HHAs.

The only rural HHA’s estimated to see a decrease are free-standing, other voluntary/non-profit HHAs. The decrease is estimated to be 0.07 percent. In total, payments are estimated to increase 0.17 percent to HHAs in rural areas and 0.19 percent to HHAs in urban areas. The only urban HHAs estimated to see a decrease are facility-based voluntary/non-profits with an estimated decrease of 0.05 percent. Overall, payments are estimated to increase 0.15 percent to HHAs in urban areas.

HHAs in the South and the West are expected to experience increases of 0.08 percent and 1.56 percent respectively from CY 2008 to CY 2009. The North and the Midwest are estimated to experience decreases of 0.08 percent and 0.44 percent respectively. It is estimated that New England, East South Central, West South Central, West North Central and Pacific HHAs will experience percentage increases of 0.36 percent, 0.02 percent, 0.34 percent, 0.61 percent, and 2.21 percent respectively. Conversely, Mid Atlantic, South Atlantic, East North Central, and Mountain area HHAs are expected to experience decreases of 0.32 percent, 0.18 percent, 0.70 percent, and 0.09 percent respectively. In general, all HHAs of varying facility size are expected to experience increases (ranging from 0.04 percent to 0.53 percent) in total payments from CY 2008 to CY 2009.
### Table 5—Impact by Agency Type

<table>
<thead>
<tr>
<th>Group</th>
<th>Percent change due to the effects of the updated wage index only</th>
<th>Percent change due to the effects of the updated wage index, the 2.9% home health market basket update, and the 2.75% reduction to the rates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Facility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free-Standing/Other Vol/NP</td>
<td>−0.22</td>
<td>−0.01</td>
</tr>
<tr>
<td>Free-Standing/Other Proprietary</td>
<td>−0.09</td>
<td>0.24</td>
</tr>
<tr>
<td>Free-Standing/Other Government</td>
<td>−0.11</td>
<td>0.07</td>
</tr>
<tr>
<td>Facility-Based Vol/NP</td>
<td>−0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>Facility-Based Proprietary</td>
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<td>0.14</td>
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<td>Facility-Based Government</td>
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</tr>
<tr>
<td>Subtotal: Freestanding</td>
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<tr>
<td>Subtotal: Vol/PNP</td>
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<td>0.05</td>
</tr>
<tr>
<td>Subtotal: Proprietary</td>
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<tr>
<td>Subtotal: Government</td>
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</tr>
<tr>
<td>Total</td>
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<td>0.15</td>
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<td><strong>Type of Facility (Rural * Only)</strong></td>
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</tr>
<tr>
<td>Free-Standing/Other Vol/NP</td>
<td>−0.22</td>
<td>0.07</td>
</tr>
<tr>
<td>Free-Standing/Other Proprietary</td>
<td>0.10</td>
<td>0.25</td>
</tr>
<tr>
<td>Free-Standing/Other Government</td>
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<td>0.01</td>
</tr>
<tr>
<td>Facility-Based Vol/NP</td>
<td>0.06</td>
<td>0.21</td>
</tr>
<tr>
<td>Facility-Based Proprietary</td>
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</tr>
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<td>Facility-Based Government</td>
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<td>0.23</td>
</tr>
<tr>
<td>Total</td>
<td>−0.12</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Type of Facility (Urban * Only)</strong></td>
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<td></td>
</tr>
<tr>
<td>Free-Standing/Other Vol/NP</td>
<td>−0.22</td>
<td>0.00</td>
</tr>
<tr>
<td>Free-Standing/Other Proprietary</td>
<td>−0.12</td>
<td>0.25</td>
</tr>
<tr>
<td>Free-Standing/Other Government</td>
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<td>0.16</td>
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<td>Facility-Based Vol/NP</td>
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<td>0.05</td>
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<tr>
<td>Facility-Based Proprietary</td>
<td>−0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>Facility-Based Government</td>
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<tr>
<td>Total</td>
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<td>0.15</td>
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<tr>
<td>*<em>Type of Facility (Urban * or Rural <em>)</em></em></td>
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<td></td>
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<tr>
<td>Rural *</td>
<td>0.01</td>
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<td>Urban *</td>
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<td>Total</td>
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<tr>
<td>**Facility Location: Region * **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>North</td>
<td>−0.30</td>
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<td>South</td>
<td>−0.25</td>
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<td>Midwest</td>
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</tr>
<tr>
<td>West</td>
<td>1.20</td>
<td>1.56</td>
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<tr>
<td>Other</td>
<td>−0.09</td>
<td>0.07</td>
</tr>
<tr>
<td>Total</td>
<td>−0.12</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Facility Location: Area of the Country</strong></td>
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</tr>
<tr>
<td>New England</td>
<td>0.15</td>
<td>0.36</td>
</tr>
<tr>
<td>Mid Atlantic</td>
<td>−0.55</td>
<td>−0.32</td>
</tr>
<tr>
<td>South Atlantic</td>
<td>−0.65</td>
<td>−0.18</td>
</tr>
<tr>
<td>East South Central</td>
<td>−0.11</td>
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<tr>
<td>West South Central</td>
<td>0.06</td>
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<td>East North Central</td>
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<tr>
<td>West North Central</td>
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</tr>
<tr>
<td>Mountain</td>
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<td>−0.09</td>
</tr>
<tr>
<td>Pacific</td>
<td>1.80</td>
<td>2.21</td>
</tr>
<tr>
<td>Other</td>
<td>−0.09</td>
<td>0.07</td>
</tr>
<tr>
<td>Total</td>
<td>−0.12</td>
<td>0.15</td>
</tr>
</tbody>
</table>
### TABLE 5—IMPACT BY AGENCY TYPE—Continued

<table>
<thead>
<tr>
<th>Facility Size (Number of First Episodes)</th>
<th>Percent change due to the effects of the updated wage index only</th>
<th>Percent change due to the effects of the updated wage index, the 2.9% home health market basket update, and the 2.75% reduction to the rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 5</td>
<td>-0.29</td>
<td>0.34</td>
</tr>
<tr>
<td>6 to 9</td>
<td>-0.41</td>
<td>0.17</td>
</tr>
<tr>
<td>10 to 14</td>
<td>-0.38</td>
<td>0.17</td>
</tr>
<tr>
<td>15 to 19</td>
<td>-0.39</td>
<td>0.19</td>
</tr>
<tr>
<td>20 to 29</td>
<td>-0.25</td>
<td>0.28</td>
</tr>
<tr>
<td>30 to 49</td>
<td>-0.10</td>
<td>0.37</td>
</tr>
<tr>
<td>50 to 99</td>
<td>0.06</td>
<td>0.50</td>
</tr>
<tr>
<td>100 to 199</td>
<td>0.07</td>
<td>0.36</td>
</tr>
<tr>
<td>200 or More</td>
<td>-0.17</td>
<td>0.04</td>
</tr>
<tr>
<td>Total</td>
<td>-0.12</td>
<td>0.15</td>
</tr>
</tbody>
</table>

**Note:** Based on a 20 percent sample of CY 2006 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.*

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

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

Dated: October 9, 2008.

**Kerry Weems,**

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 24, 2008.

**Michael O. Leavitt,**

Secretary.

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

**Addendum A—CY 2009 Wage Index for Rural Areas by CBSA: Applicable Pre-floor and Pre-Reclassified Hospital Wage Index**

<table>
<thead>
<tr>
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2008–N–0572]


AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the burden hours required for the Animal Generic Drug User Fee Cover Sheet, Form FDA 3728 and the timeframe requirement under the Animal Generic Drug User Fee Act of 2008 (AGDUFA) (21 U.S.C. 379j–21(a)) for implementing the new user fee cover sheet Form FDA 3728.

DATES: Fax written comments on the collection of information by November 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or email to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and “Implementation of the Animal Generic Drug User Fee Act of 2008 (21 U.S.C. 379j–21(a)); User Fee Cover Sheet Form 3728; Emergency Request.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The Federal Food, Drug, and Cosmetic Act (the act), as amended by AGDUFA authorizes FDA to collect user fees: (1) For certain abbreviated applications for a generic new animal drug, (2) on certain generic new animal drug products, and (3) on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. Because the submission of user fees concurrently with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728, the Animal Generic Drug User Fee Cover Sheet, is designed to provide the minimum necessary information in order to: (1) Determine whether a fee is required for review of an application, (2) determine the amount of fee required, and (3) account for and track user fees.

FDA estimates the burden of this collection of information as follows:

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<th>21 U.S.C. 379j–21.</th>
<th>No. of Respondents</th>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are generic new animal drug applicants. Based on FDA’s database system, there are an estimated 20 sponsors of new animal drugs potentially subject to AGDUFA. The

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

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