TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
80.39	41	106	4,346[2]	0.25	1,086

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to a clerical error, the total annual records that appeared in tables 1 and 2 in the FEDERAL REGISTER notice of April 13, 2001 (66 FR 19175), was incorrect. Tables 1 and 2 of this document contains the correct total.

The estimated total annual burden for this information collection is 2,172 hours. Over the period fiscal year (FY) 1998 to 2000, FDA processed an average of 4,346 requests for certification of batches of color additives. Approximately 41 different respondents submitted requests for certification each year over the period FY 1998 to 2000. FDA obtained the estimates for the length of time necessary to prepare certification requests and accompanying samples and to comply with recordkeeping requirements from industry program area personnel.

Dated: June 22, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16325 Filed 6–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1147–NC]

RIN 0938–AK51

Medicare Program; Update to the Prospective Payment System for Home Health Agencies for FY 2002

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period 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 agencies.

DATES: *Effective Date:* The rate updates in this notice with comment period are effective on October 1, 2001.

Comment Period: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 28, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1147–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1147–NC. Comments received timely will be available for public inspection as they are received, generally beginning appropriately 3 weeks after publication of a document, in Room C5–12–08 of the headquarters Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (410) 786–7197).

FOR FURTHER INFORMATION CONTACT:

Bob Wardwell (Project Manager), (410) 786–3254.

Susan Levy (Policy), (410) 786–9364.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background; Recent Legislation on Payment to Home Health Agencies

A. Balanced Budget Act of 1997

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. Until the implementation of a home health prospective payment system (HH PPS) on October 1, 2000, home health agencies (HHAs) received payment under a cost-based reimbursement system. Section 4603 of the BBA governed the development of HH PPS.

Section 4603(a) of the BBA provides the authority for the development of a PPS for all Medicare-covered home health services provided under a plan of care that were paid on a reasonable cost basis by adding section 1895, entitled ''Prospective Payment For Home Health Services,'' to the Social Security Act (the Act).

Section 1895(b)(1) of the Act requires the Secretary to establish a PPS for all costs of home health services paid under Medicare.

Section 1895(b)(2) of the Act requires the Secretary in defining a prospective payment amount to consider an appropriate unit of service and the number, type, and duration of visits furnished within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires that (1) the computation of a standard prospective payment amount include all costs of 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)(C) of the Act requires the Secretary to reduce the prospective payment amounts if the

Secretary accounts for an addition or adjustment to the payment amount made in the case of outlier payments.

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 adjustment factor that explains a significant amount of the variation in cost 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 the furnishing of home health services in a geographic area compared to the national average applicable level. These wage-adjustment factors may be the factors used by the Secretary for the different area wage levels for purposes of section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to grant additions or adjustments to the payment amount otherwise made 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 cannot exceed 5 percent of total payments projected or estimated.

Section 1895(b)(6) of the Act provides for the proration of prospective payment amounts between the HHAs involved in the case of a patient electing to transfer or receive services from another HHA within the period covered by the prospective payment amount.

Section 1895(d) of the Act limits review of certain aspects of the HH PPS. Specifically, there is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

- The establishment of the transition period under section 1895(b)(1) of the Act.
- The definition and application of payment units under section 1895(b)(2) of the Act.
- The computation of initial standard prospective amounts under section 1895(b)(3)(A) of the Act (including the reduction described in section 1895(b)(3)(A)(ii) of the Act).
- The establishment of the adjustment for outliers under section 1895(b)(3)(C) of the Act.
- The establishment of case-mix and area wage adjustments under section 1895(b)(4) of the Act.
- The establishment of any adjustments for outliers under section 1895(b)(5) of the Act.

Section 4603(b) of the BBA amends section 1815(e)(2) of the Act by eliminating periodic interim payments for HHAs effective October 1, 2000.

Section 4603(c) of the BBA sets forth the following conforming amendments:

- Section 1814(b)(1) of the Act is amended to indicate that payments under Part A will also be made under section 1895 of the Act.
- Section 1833(a)(2)(A) of the Act is amended to require that home health services, other than a covered osteoporosis drug, are paid under HH PPS.
- Section 1833(a)(2) of the Act is amended by adding a new subparagraph (G) regarding payment of Part B services at section 1861(s)(10)(A) of the Act.
- Section 1842(b)(6)(F) is added to the Act and section 1832(a)(1) of the Act is amended to include a reference to section 1842(b)(6)(F) of the Act, both governing the consolidated billing requirements.

B. Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999

On October 21, 1998, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (OCESAA), Pub. L. 105–277, was enacted.

Section 5101(c) of the OCESAA amends section 1895(a) of the Act by removing the transition into the HH PPS by cost-reporting periods and requiring all HHAs to be paid under HH PPS effective upon the implementation date of the system.

Section 5101(c) of the OCESAA also modifies the effective date of the budget-neutrality targets for HH PPS by amending section 1895(b)(3)(A)(ii) of the Act. Section 1895(b)(3)(A) of the Act, as amended, requires that the standard prospective payment limitation amounts be budget neutral.

Section 5101(d)(2) of the OCESAA also modifies the statutory provisions dealing with the home health market basket percentage increase. For FY 2002 or FY 2003, sections 1895(b)(3)(B)(i) and (b)(3)(B)(ii) of the Act, as modified, require that the standard prospective payment amounts be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute requires the rates to be increased by the applicable home health market basket index change.

Section 5101(c)(2) of the OCESAA amends section 4603(d) of the BBA by changing the effective date language for the HH PPS and the other changes made by section 4603 of the BBA. Section 4603(d) of the BBA now provides that ''Except as otherwise provided, the amendments made by this section shall apply to portions of cost reporting periods occurring on or after October 1, 2000.'' This change required all HHAs to be paid under HH PPS effective October 1, 2000.

C. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999

Section 305 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106–113, refines the consolidated billing requirements under HH PPS. The BBRA excludes durable medical equipment (DME) from the home health consolidated billing requirements.

Section 306 of BBRA amends the statute to provide a technical correction clarifying the applicable market basket increase for HH PPS in each of FY 2002 and FY 2003. The technical correction clarifies that the update in HH PPS in FY 2002 and FY 2003 will be the home health market basket minus 1.1 percentage points.

D. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

Section 501 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554, sets forth a 1 year additional delay in application of the 15 percent reduction on payment limits for home health services. This section also amends section 302(C) of the BBRA to now require a Report to Congress by the Comptroller General of the United States no later than April 1, 2002 on the 15 percent reduction issue.

Section 502 of the BIPA sets forth a special rule for payment for FY 2001 based on adjustment of the published prospective payment amounts. This special payment rule has the effect of restoring the market basket reduction already incorporated into the HH PPS rates. The adjustment provides the effect of a full market basket adjustment to the HH PPS rates for FY 2001. The statute also requires paying episodes and national per-visit amounts for low utilization payment adjustments (LUPAs) ending on or after April 1, 2001 and before October 1, 2001 an additional 2.2 percent.

Section 508 of the BIPA also requires, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) on or after April 1, 2001 and before April 1, 2003, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for the services by 10 percent. The statute waives budget

neutrality for purposes of this increase since it specifically states that the Secretary 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.

II. Provisions of This Notice With Comment Period

A. National Standardized 60-Day Episode Rate

Medicare HH PPS has been effective 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 Medicare HH PPS is a national standardized 60-day episode rate. The standardized 60-day episode rate for FY 2001 published in the final rule in Table 5 (65 FR 41184) was $2,115.30. As discussed in the budget neutrality analysis in the July 3, 2000 final rule, phasing in all patients to HH PPS at the October 1, 2000 effective date for all HHAs created an anomaly in terms of increasing the projected number of episodes in the first year of HH PPS. Because all patients who were already under a home health plan of care at the beginning of FY 2001 were deemed to have started a new episode on October 1, 2000, more episodes are projected to occur during the first year compared to what would have been projected otherwise. As discussed in the July 3, 2000 final rule accounting for the anomaly of the first year of PPS, the rates for FY 2001 would have been $79 higher if the anomaly did not exist.

As set forth in the July 3, 2000 final rule at 42 CFR 484.220, we adjust the national standardized 60-day episode rate by case-mix and wage index based on the site of service for the beneficiary. The FY 2002 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 July 3, 2000 final rule. 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 applicable adjustments.

For FY 2002, we use again the design and case-mix methodology described in section III.G of the HH PPS July 3, 2000 final rule (65 FR 41192 through 41203). For FY 2002, we base the wage index adjustment to the labor portion of the PPS rates on the most recent pre-floor and pre-reclassified hospital wage index available at the time of publication of this notice, which is discussed in section II.D of this notice with comment period.

As discussed in the July 3, 2000 home health 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. 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 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 available at the time of publication of this notice, as discussed in section II.D of this notice with comment period.

As outlined in the July 3, 2000 HH PPS final rule, 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 (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment and the final percentage payment on the submission of the claim for the episode, as discussed in regulations 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 the rate level at which Medicare will pay the claim for the fiscal period.

As discussed in the HH PPS July 3, 2000 final rule, we may 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.
- A significant change in condition adjustment as set forth in § 484.205(e) and § 484.237.
- An outlier payment as set forth in § 484.205(f) and § 484.240.

This notice with comment period reflects the updated FY 2002 rates that are effective October 1, 2001.

B. Update to the Home Health Market Basket Index

Section 1895(b)(3)(B)(ii) of the Act requires the standard prospective payment amounts to be increased by a factor equal to the home health market basket minus 1.1 percentage points for FY 2002. This has been codified in regulations in § 484.225.

- *FY 2001 Adjustments*

As discussed in section I.D of this notice with comment period, section 502 of the BIPA sets forth a special rule for payment for FY 2001 based on adjusted prospective payment amounts. The adjustment provides the effect of a full market basket adjustment to the PPS rates for FY 2001. Section 502 of the BIPA specifically states, ''Notwithstanding the amendments made by subsection (a), for purposes of making payments under section 1895(b) of the Act (42 U.S.C. 1395fff(b)) for home health services for FY 2001, the Secretary of Health and Human Services shall—(A) with respect to episodes and visits ending on or after October 1, 2000, and before April 1, 2001, use the final standardized and budget neutral prospective payment amounts for 60 day episodes and standardized average per-visit amounts for FY 2001 as published by the Secretary in the July 3, 2000 **Federal Register** (65 FR 41128–41214); and (B) with respect to episodes and visits ending on or after April 1, 2001, and before October 1, 2001, use these amounts increased by 2.2 percent.'' Thus, the statute requires paying episodes and national per-visit amounts for LUPAs ending on or after April 1, 2001 and before October 1, 2001 by an additional 2.2 percent. Due to this legislation, during FY 2001 Medicare pays $2,115.30 for episodes ending on or before March 31, 2001 and Medicare pays $2,161.84 (= $2,115.30 * 1.022) for episodes ending on or after April 1, 2001 and before October 1, 2001, prior to any applicable adjustment. We implemented this provision on April 1, 2001 through the HCFA Program Memorandum, ''Restoration of Full Home Health Market Basket Update for Home Health Services for Fiscal Year 2001 and Temporary 10 Percent Payment Increase for Home Health Services Furnished in a Rural Area for 24 Months Under the Home Health Prospective Payment System (HH PPS)'' (Transmittal A–01–06, issued January 16, 2001).

• *FY 2002 Adjustments*

In calculating the annual update for the FY 2002 60-day episode rates, we first looked at the FY 2001 rates as a starting point. We took into account two factors in determining the starting point for the FY 2001 rates: section 502 of the BIPA, enacted mid-FY 2001, that restored the full market basket for FY 2001; and the first-year anomaly associated with increased payments at the start-up of HH PPS. In determining the starting point for the annual update for FY 2002, we adjusted the standardized 60-day episode rate for FY 2001 to offset the anomaly of the first year of PPS ($2,115.30 + $79 = $2,194.30). We then divide that amount by 1 minus 1.1 percent ($2,194.30/(1–0.011)) to restore the full market basket. This yields the starting point for the FY 2001 rates with the full market basket adjustment for FY 2001 required to calculate the update for FY 2002.

The annual update for FY 2002 is the home health market basket minus 1.1 percentage points as defined in section 1895(b)(3)(B)(ii) of the Act. The home health market basket increase for FY 2002 is 3.6 percent. In order to calculate the updated FY 2002 rates, we multiplied the FY 2001 amount that we restored to the full market basket by 1 plus the home health market basket minus 1.1 percentage points (1+0.036 − 0.011 = 1.025) to yield the updated national 60-day episode amount for FY 2002 ($2,274.17).

NATIONAL 60-DAY EPISODE AMOUNTS UPDATED BY THE HOME HEALTH MARKET BASKET MINUS 1.1% FOR FY 2002 PRIOR TO CASE-MIX ADJUSTMENT, WAGE INDEX ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY OR APPLICABLE PAYMENT ADJUSTMENT

Total standardized prospective payment amount per 60-day episode for FY 2001 ($2,115.30) published in July 3, 2000 **Federal Register** plus additional $79 to offset implementation of first year of PPS	Restore to full Market Basket	Multiply by 1 plus the HH Market Basket minus 1.1%	Final updated 60-day episode payment amount for FY 2002
$2,194.30	/(1–0.011)	x1.025	$2,274.17

• *National Per-Visit Amounts Used to Pay LUPAs and Compute Imputed Costs Used in Outlier Calculations*

As discussed previously in this notice with comment period, the policies governing the LUPAs and outlier calculations set forth in the July 3, 2000 HH PPS final rule will continue during FY 2002. In calculating the annual update for the FY 2002 national per-visit amounts we use to pay LUPAs and to compute the imputed costs in outlier calculations, we again looked at the FY 2001 rates as a starting point. We used the same methodology that we used to restore the 60-day episode rate to the full market basket for FY 2001 to restore the national per-visit amounts to calculate the LUPAs and to impute costs in the outlier calculations. We then multiplied those amounts by 1 plus the home health market basket minus 1.1 percentage points to yield the updated per-visit amounts for each home health discipline for FY 2002. (See table below.)

NATIONAL PER-VISIT AMOUNTS FOR LUPAS AND OUTLIER CALCULATIONS UPDATED BY THE HOME HEALTH MARKET BASKET MINUS 1.1% FOR FY 2002 PRIOR TO WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY OR THE APPLICABLE PAYMENT ADJUSTMENT

Home Health Discipline type	Final standardized per-visit amounts per 60-day episode for FY 2001 for LUPAs published in July 3, 2000 **Federal Register**	Restore to full Market Basket	Multiply by 1 plus Home Health Market Basket minus 1.1%	Final standardized per-visit payment amount per discipline for FY 2002 for LUPAs
Home Health Aide	$ 43.37	/(1–0.011)	x1.025	$ 44.95
Medical Social Services	153.55	/(1–0.011)	x1.025	159.14
Occupational Therapy	105.44	/(1–0.011)	x1.025	109.28
Physical Therapy	104.74	/(1–0.011)	x1.025	108.55
Skilled Nursing	95.79	/(1–0.011)	x1.025	99.28
Speech-Language Pathology	113.81	/(1–0.011)	x1.025	117.95

C. Rural Add-On as Required by the BIPA

Section 508 of the BIPA requires, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) on or after April 1, 2001 and before April 1, 2003, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for services by 10 percent. The statute waives budget neutrality related to this provision as it specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to home health services furnished during a period to offset the increase in payments resulting in the application of this section of the statute. Section 508 provides for payment for the national standardized episode amounts and LUPA national per-visit amounts for the entire FY 2002 by an additional 10 percent for home health services furnished in rural areas where the site of service for the beneficiary is a non-MSA area. The applicable case-mix and wage index adjustment is subsequently applied to the 60-day episode amount for the provision of home health services where the site of service is the non-MSA area of the beneficiary. Similarly, the applicable wage index adjustment is subsequently applied to the LUPA per-visit amounts

adjusted for the provision of home health services where the site of service for the beneficiary is a non-MSA area. We implemented this provision for FY 2001 on April 1, 2001 through the HCFA Program Memorandum, ''Restoration of Full Home Health Market Basket Update for Home Health Services for Fiscal Year 2001 and Temporary 10 Percent Payment Increase for Home Health Services Furnished in a Rural Area for 24 Months Under the Home Health Prospective Payment System (HH PPS)'' (Transmittal A–01–06 issued January 16, 2001). (See FY 2002 add-on noted in tables below:)

FY 2002 RURAL ADD-ON TO 60-DAY EPISODE PAYMENT AMOUNTS FOR BENEFICIARIES WHO RESIDE IN A NON-MSA AREA PRIOR TO CASE-MIX ADJUSTMENT, WAGE INDEX ADJUSTMENT BASED ON THE SITE OF SERVICE OF THE BENEFICIARY, OR APPLICABLE PAYMENT ADJUSTMENT

Payment amount per 60-day episode for FY 2002	10% add-on	Final payment amount per 60-day episode for FY 2002 for a beneficiary who resides in a rural non-MSA area.
$2,274.17	x1.10	$2,501.59

FY 2002 RURAL ADD-ON TO LUPA PER-VISIT AMOUNTS PRIOR TO WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE OF THE BENEFICIARY WHO RESIDES IN A NON-MSA AREA OR PAYMENT APPLICABLE ADJUSTMENT

Home health discipline type	Final per-visit payment amount per 60-day episodes for FY 2002 for LUPAs	10% add-on	Final per-visit amount per 60-day episodes for FY 2002 for LUPAs for a payment beneficiary who resides in a non-MSA area
Home Health Aide	$44.95	x1.10	$49.45
Medical Social Services	159.14	x1.10	175.05
Occupational Therapy	109.28	x1.10	120.21
Physical Therapy	108.55	x1.10	119.41
Skilled Nursing	99.28	x1.10	109.21
Speech-Language Pathology	117.95	x1.10	129.75

D. 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 HH PPS to account for area wage differences. We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the geographic area in which the beneficiary received home health services. 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).

As discussed previously and set forth in the July 3, 2000 final rule, the statute provides that the wage adjustment factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustment factors. Again, as discussed in the July 3, 2000 final rule, we used the most recent pre-floor and pre-reclassified hospital wage index available at the time of publication of this notice to adjust the labor portion of the HH PPS rates based on the geographic area in which the beneficiary receives the home health services. We believe the use of the most recent available pre-floor and pre-reclassified hospital wage index data results in the appropriate adjustment to the labor portion of the costs as required by statute. (See addenda A and B of this notice with comment period, respectively, for the rural and urban hospital wage indexes.)

III. 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 incorporates a statement of finding and its reasons in the notice issued.

We believe it is unnecessary to undertake proposed notice and comment rulemaking as the statute requires annual updates to the HH PPS rates, the methodologies used to update the rate have been previously subject to public comment, and this notice reflects the application of previously established methodologies. Further, the new rural add-on and adjustments to FY 2001 HH PPS rates that were required by the BIPA prior to this required annual update for the FY 2002 PPS rates are dictated by statute and do not require an exercise of discretion. Therefore, for good cause, we waive prior notice and comment procedures. As indicated previously, we are, however, providing a 60-day comment period for public comment.

IV. Collection of Information Requirements

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. 3501 *et seq.*).

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of

this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The update set forth in this notice applies to Medicare payments under HH PPS in FY 2002. Accordingly, the analysis that follows describes the impact in FY 2002 only. We estimate that there will be an additional $350 million in FY 2002 expenditures attributable to the FY 2002 market basket increase of 2.5 percent.

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 MSA and has fewer than 50 beds. We have determined that this notice with comment period will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $10 million or less annually. For purposes of the RFA, we consider most HHAs to be small entities. Individuals and States are not included in the definition of a small entity. As stated above, this notice with comment period provides an update to all HHAs for FY 2002 as required by statute. This notice with comment period reflects the statutory update to the HH PPS rates published in the July 3, 2000 final rule as amended by the BIPA of 2000, but will have a significant positive effect upon small entities.

Section 202 of the Unfunded Mandate 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. We believe this notice with comment period will not mandate expenditures in that amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this 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

In accordance with the requirements of section 1895(b)(3) of the Act, we publish an update for each subsequent fiscal year that will provide an update to the payment rates. Section 1895(b)(3) of the Act requires us, for FY 2002, to increase the prospective payment amounts by the home health market basket increase minus 1.1 percentage points. The home health market basket increase for FY 2002 is 3.6 percent. Taking into account the provisions of section 1895(b)(3) of the Act, the increase for FY 2002 is 2.5 percent (that is, 3.6 percent–1.1 percent). This notice with comment period is confined to implementing the home health market basket increase for FY 2002. For the sake of clarity, we have also included the amounts as increased by the rural add-on provision under section 508 of the BIPA. We implemented the rural add-on amounts for FY 2002, effective on April 1, 2001 through the HCFA Program Memorandum, ''Restoration of Full Home Health Market Basket Update for Home Health Services for Fiscal Year 2001 and Temporary 10 Percent Payment Increase for Home Health Services Furnished in a Rural Area for 24 Months Under the Home Health Prospective Payment System (HH PPS)'' (Transmittal A–01–06, issued January 16, 2001). Section 508 of the BIPA provides a 10 percent rural add-on for home health services furnished to beneficiaries whose site of service is a rural area (non-MSA) for 24 months beginning with episodes ending on or after April 1, 2001 and before April 1, 2003.

1. Effects on the Medicare Program

This notice with comment period merely provides a percentage update to all Medicare HHAs. Therefore, we have not furnished any impact tables. We increase the payment to each Medicare HHA equally by the home health market basket update for FY 2002, as required by statute. There is no differential impact among provider types. The impact is in the aggregate. We estimate that there will be an additional $350 million in FY 2002 expenditures attributable to the FY 2002 market basket increase of 2.5 percent. Thus, the anticipated expenditures outlined in this notice exceed the $100 million annual threshold for a major rule as defined in Title 5, U.S.C., section 804(2).

As discussed previously, several sections of the BIPA impact the estimated Medicare home health expenditures in FY 2002. Section 501 of the BIPA sets forth an additional 1-year delay in application of the 15-percent reduction. The delay of the 15-percent reduction for 1 year results in an additional $890 million in estimated Medicare home health expenditures in FY 2002. Section 502 of the BIPA restores the full home health market basket update for FY 2001. We estimate that there will be an additional $170 million in FY 2002 expenditures due to the restoration of the full home health market basket in FY 2001. Section 508 of the BIPA requires a 10-percent payment increase to the episode and per-visit payment amounts under the HH PPS for Medicare home health services furnished in a rural area for a 24-month period. The 10-percent rural add-on provides an additional payment for Medicare home health services that are provided where the site of service of the beneficiary is a rural area. The 10-percent rural add-on increases estimated Medicare home health expenditures by $310 million in FY 2002. (Source: President's Fiscal 2002 Budget) (See tables below.)

Provision of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)	Additional FY 2002 Medicare Home Health Estimated Expenditures Due to the BIPA Provision
Section 501—additional year delay of 15-percent reduction	$890 million.
Section 502—restoration of full home health market basket in FY 2001	$170 million.
Section 508—10-percent rural add-on for Medicare home health services furnished in a rural area	$310 million.

FY 2002 Update to Home Health PPS Rates Required by the Act	Additional FY 2002 Medicare Home Health Estimated Expenditures Due to Annual Update Required by Law
Section 1895(b)(3)(B) of the Act requires HH PPS rates increased by home health market basket minus 1.1 percentage points in FY 2002 (2.5% increase).	$350 million.

2. Effects on Providers

This notice with comment period will have a positive effect on providers of Medicare home health services by increasing their rate of Medicare payment. We do not anticipate specific effects on other providers. This notice with comment period reflects the statutorily required annual update to the HH PPS rates published in the July 3, 2000 final rule. Also, as discussed above, this notice with comment period provides an update to all Medicare HHAs. We do not believe there is a differential impact due to the consistent and aggregate nature of the update.

C. Alternatives Considered

As discussed in section II, this notice with comment period reflects an annual update to the HH PPS rates as required by statute. Due to the lack of discretion provided in the statutory requirements governing this notice with comment period, we believe the statute provides no latitude for alternatives other than the approach set forth in this notice reflecting the FY 2002 annual update to the HH PPS rates. Also, as discussed in section II for clarification, this notice addresses the 10 percent rural add-on required under section 508 of the BIPA for home health services furnished to beneficiaries who reside in a rural non-MSA area. Other than the positive effect of the market basket increase, this notice with comment will not have a significant economic impact nor will it impose an additional burden on small entities. When a regulation or notice imposes additional burden on small entities, we are required under the RFA to examine alternatives for reducing burden. Since this notice with comment period will not impose an additional burden, we have not examined alternatives.

D. Conclusion

We have examined the economic impact of this notice with comment period on small entities and have determined that the economic impact is positive, significant, and that all HHAs will be affected. To the extent that small rural hospitals are affiliated with HHAs, the impact on these facilities will also be positive. Finally, we have determined that the economic effects described above are largely the result of the BIPA provisions which this notice serves to announce.

We continue to analyze the appropriateness and accuracy of payments for differing case mixes. In the fall of 2001, we intend to undertake a re-evaluation of the OASIS reporting system's utility in ensuring more accurate and equitable PPS payments.

In accordance with the provisions of notice with comment Executive Order 12866, this 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: March 15, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: April 23, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–16384 Filed 6–28–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1186–N]

Medicare Program; Public Meeting for New Clinical Laboratory Tests—Payment Determinations for Calendar Year 2002

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to discuss the assignment of payment rates for specific new Current Procedural Terminology (CPT) codes for clinical laboratory tests. These codes will be included in Medicare's Clinical Laboratory Fee Schedule for calendar year 2002, which will be effective on January 1, 2002. The meeting is directed towards the discussion of technical issues relating to payment determinations for a specified list of new codes, and discussion will be limited to the codes on that list.

DATES: *The Meeting:* August 6, 2001, from 8:30 a.m. until 4 p.m., E.D.T.

Deadline for Registration: Individuals may register by sending a fax to the attention of Anita Greenberg at (410) 786–0169, no later than July 25, 2001. Please provide name, company name, address, telephone number, and indicate whether interested in making an oral presentation.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, should notify Anita Greenberg at fax number (410) 786–0169 or at telephone number (410) 786–4601 so that accommodations can be made.

ADDRESSES: *The Meeting:* The meeting will be held at the Health Care Financing Administration (HCFA) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

Website: A summary of the meeting will be posted on HCFA's Internet website (*www.hcfa.gov*) within 1 month after the meeting.

General Information: The meeting will be held in a government building; therefore, security measures will be applicable. Anyone without government identification will need to present photo identification, sign-in, and supply registration information.