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December 2, 2010

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander M. Levin
Acting Chairman
The Honorable Dave Camp
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), entitled “Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices” (RIN: 0938-AP88). We received the rule on November 2, 2010. It was published in the *Federal Register* as a final rule on November 17, 2010. 75 Fed. Reg. 70,372.

The final rule sets forth an update to the Home Health Prospective Payment System (HH PPS) rates, including: the national standardized 60-day episode rates, the national per-visit rates, the nonroutine medical supply (NRS) conversion factors, and

the low utilization payment amount (LUPA) add-on payment amounts, under the Medicare prospective payment system for HHAs effective January 1, 2011. The final rule also updates the wage index used under the HH PPS and updates the HH PPS outlier policy. In addition, the final rule revises the home health agency (HHA) capitalization requirements and finalizes a 3.79 percent reduction to rates for CY 2011 to account for changes in case-mix, which are unrelated to real changes in patient acuity. Finally, this rule incorporates new legislative requirements regarding face-to-face encounters with providers related to home health and hospice care.

The final rule, a major rule under the Congressional Review Act (CRA), has an announced effective date of January 1, 2011. CRA requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. 801(a)(3)(A). We received the rule on November 2, 2010, and it was not published in the *Federal Register* until November 17, 2010. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of CMS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that, with the exception of the delay in the rule's effective date, CMS complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
Department of Health and
Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; HOME HEALTH PROSPECTIVE PAYMENT SYSTEM
RATE UPDATE FOR CALENDAR YEAR 2011; CHANGES IN CERTIFICATION
REQUIREMENTS FOR HOME HEALTH AGENCIES AND HOSPICES"
(RIN: 0938-AP88)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. CMS estimates that the net impact of the final rule will be approximately \$960 million in CY 2011 savings. CMS estimates the distributional effects of an updated wage index will account for a \$20 million increase, the 1.1 percent home health market basket update will account for a \$210 million increase, while the 3.79 percent case-mix adjustment applicable to the national standardized 60-day episode rates will account for a \$700 million decrease, and the 2.5 percent returned from the outlier provisions of the Affordable Care Act will result in a \$490 million decrease.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

CMS determined that the final rule will have a significant economic impact on a substantial number of small entities. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or revenues, and approximately 95 percent of home health agencies (HHAs) are considered to be small businesses. CMS amended the proposed rule that would have implemented two successive years of payment reductions, and instead in the final rule finalized only the first year's reduction for CY 2011 and will study additional data.

CMS determined that the final rule would not have a significant economic impact on the operations of small rural hospitals.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

CMS determined that the final rule is not anticipated to have an effect on state, local, or tribal governments in the aggregate, or on the private sector, of \$135 million or more.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

On July 23, 2010, CMS published a notice of proposed rulemaking in the *Federal Register*. 75 Fed. Reg. 43,236. CMS received approximately 500 items of correspondence from the public. These included numerous comments from various trade associations and major health-related organizations, as well as from HHA's, hospitals, other providers, suppliers, practitioners, advocacy groups, consulting firms and private citizens. CMS responded to the comments in the final rule. 75 Fed. Reg. 70,372.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The final rule contains information collection requirements under the Act. CMS solicits comments on the requirements in the final rule. The final rule clarifies requirements for therapy coverage, already approved by the Office of Management and Budget (OMB) Number 0938-1083, which CMS is revising, and CMS does not believe these proposed requirements place any new document requirements on HHAs. The final rule's requirements regarding HHA capitalization will result in an estimated total burden hours of 2,250 hours. The final rule's requirements regarding the home health face-to-face encounter requirement, which will be included in revised OMB Number 0938-1083, will result in an estimated total one-time form development burden of 4,716 hours and an estimated physician burden for documenting, signing, and dating encounter of 243,868 hours. The final rule's requirements for hospice certification changes will result in the estimated one-time burden of 1,714 hours for developing the attestation form, 3,811 hours for recertifications at 180 days or beyond, and 14,447 annual burden hours for physicians to include the benefit period dates on the certification or recertification. Finally, CMS is revising its burden under OMB Number 0938-1066 to reflect the burden hours on HHAs to select a survey vendor to conduct HHCAHPS (Home Healthcare Consumer Assessment of Healthcare Providers and Services) on behalf of the HHA, which will result in an estimated annual burden on HHAs of 158,240 hours.

Statutory authorization for the rule

The final rule is authorized by section 1895 of the Social Security Act, as amended.

Executive Order No. 12,866 (Regulatory Planning and Review)

CMS determined that this rule is an economically significant rule under Executive Order 12,866 and prepared a regulatory impact analysis that presents the costs and benefits of the rulemaking. The final rule was reviewed by OMB under the Executive Order.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule will not have substantial direct effects on the rights, roles, and responsibilities of states, local, or tribal governments.