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December 2, 2008

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

The Honorable John D. Dingell
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Charles B. Rangel
Chairman
The Honorable Jim McCrery
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payments Rates; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants—Clarification of Provider and Supplier Termination Policy Medicare and Medicaid Programs: Changes to the Ambulatory Surgical Center Conditions for Coverage*

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 and Medicaid Services (CMS), entitled “Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payments

Rates; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants—Clarification of Provider and Supplier Termination Policy Medicare and Medicaid Programs: Changes to the Ambulatory Surgical Center Conditions for Coverage” (RINs: 0938-AP17, 0938-AL80, 0938-AH17). The final rule is, in fact, three rules. We received the rules on October 31, 2008. The rules were published in the *Federal Register* as a “final rule with comment period; final rules” on November 18, 2008. 73 Fed. Reg. 68,502.

There is one final rule with comment period (RIN: 0938-AP17). This final rule revises the Medicare hospital outpatient prospective payment system to implement changes made by the Medicare Improvement for Patients and Providers Act of 2008, Public Law 110-275, July 15, 2008, and changes arising from experience with the system. This final rule also revises the Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from experience with the system. These changes are applicable to services furnished on or after January 1, 2009.

There are two additional final rules included with this rule (RINs: 0938-AL80, and 0938-AH17). One final rule updates the ASC conditions for coverage to “promote and protect patient health and safety.” This rule is effective on May 18, 2009. The other final rule clarifies policy statements regarding the Secretary’s ability to terminate Medicare providers and suppliers (transplant centers) during an appeal of a determination that affects participation in the Medicare program. This final rule is effective on December 18, 2008. Neither of these two rules are major rules under the Congressional Review Act (CRA).

The final rule with comment period, a major rule under CRA, has an announced effective date of January 1, 2009. 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 October 31, 2008, but it was not published in the *Federal Register* until November 18, 2008. Therefore, the final rule does not have the required 60 day delay in its effective date.

Enclosed is our assessment of the CMS’s compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the final rule with comment period, i.e., the major rule. Our review 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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236.

signed

Robert J. Cramer
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 AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM: CHANGES TO THE HOSPITAL OUTPATIENT
PROSPECTIVE PAYMENT SYSTEM AND CY 2009 PAYMENT RATES; CHANGES
TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM AND
CY 2009 PAYMENTS RATES; HOSPITAL CONDITIONS OF PARTICIPATION"
(RIN: 0938-AP17)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule. CMS estimates that the total increase (from changes in this final rule as well as enrollment, utilization, and case-mix changes) in expenditures under the hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2009 compared to CY 2008 will be approximately \$1.6 billion. CMS also estimates that the effects of the changes to the ambulatory surgical center (ASC) payment system provisions for CY 2009 will have no net effect on Medicare expenditures in CY 2009 compared to the level of expenditures in CY 2008.

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

CMS estimated that the final rule will have a significant economic effect on small businesses, including a substantial number of rural hospitals. CMS prepared a Final Regulatory Analysis for the final rule that complies with the requirements of the Act.

(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 does not contain either an intergovernmental or private sector mandate, as defined in Title II, of more than \$130 million in any one year.

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

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

CMS promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. CMS published a proposed rule in the *Federal Register* on July 18, 2008, for the CY 2009 OPPS/ASC payment system.

73 Fed. Reg. 41,416. On August 11, 2008, CMS published a correction notice in the *Federal Register* to replace Table 30 included in the proposed rule. 73 Fed. Reg. 46,575. CMS received almost 2,400 comments to the proposed rule and responded to the comments in the final rule.

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

This final rule contains information collections within the framework of the Paperwork Reduction Act. CMS published a notice requesting comments on the collection of information requirements accompanying the proposed rule and submitted requests to the Office of Management and Budget (OMB) in accordance with the Act, which were approved by OMB. Some of the revisions to the proposed rule affect the collections of information. Therefore, CMS has requested public comments on the paperwork burden with respect to these revisions.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority in sections 1102 and 1871 of the Social Security Act, 42 U.S.C. §§ 1302 and 1395hh.

Executive Order No. 12,866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the Order.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication. CMS estimates that the OPPS payments to governmental hospitals, including state and local governmental hospitals, will increase by 4.4 percent under this final rule. The provisions relating to ASC payments will not affect payments to governmental hospitals.