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December 8, 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: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals*

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: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates” (RINS: 0938-AP82; 0938-AP80). We received the rule on November 2, 2010. It was published in the *Federal Register* as “final rule with comment period; final rules; and interim final rule with comment period” on November 24, 2010. 75 Fed. Reg. 71,800. The publication in the *Federal Register* included two final non-major rules relating to payments to hospitals for direct graduate medical education and indirect medical education

costs; and new limitations on certain physician referrals to hospitals in which they have an ownership or investment interest.

The final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) to implement applicable statutory requirements and changes arising from CMS's experience with this system and to implement certain provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act). The final rule with comment period describes the changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system for services furnished on or after January 1, 2011. In addition, this final rule with comment period updates the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from CMS's experience with this system and to implement certain provisions of the Affordable Care Act. In this final rule with comment period, CMS sets forth the applicable relative payment weights and amounts for services furnished in ASCs, specific HCPCS codes to which these changes apply, and other pertinent ratesetting information for the ASC payment system for services furnished on or after January 1, 2011.

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 24, 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: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CY 2011 PAYMENT RATES; AMBULATORY SURGICAL CENTER PAYMENT SYSTEM AND CY 2011 PAYMENT RATES; PAYMENTS TO HOSPITALS FOR GRADUATE MEDICAL EDUCATION COSTS; PHYSICIAN SELF-REFERRAL RULES AND RELATED CHANGES TO PROVIDER AGREEMENT REGULATIONS; PAYMENT FOR CERTIFIED REGISTERED NURSE ANESTHETIST SERVICES FURNISHED IN RURAL HOSPITALS AND CRITICAL ACCESS HOSPITALS"
(RINS: 0938-AP82; 0938-AP80)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule with comment period. CMS estimates that the total increase (from changes in the final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2011 compared to CY 2010 will be approximately \$3.2 billion. CMS also estimates that the total increase (from changes in the final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the ambulatory surgical center (ASC) payment system provisions for CY 2011 compared to CY 2010 will be approximately \$230 million.

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

CMS determined that the final rule with comment period will have a significant economic impact on small entities, including a substantial number of small rural hospitals. CMS prepared a Final Regulatory Flexibility Analysis for the final rule with comment period.

(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 with comment period will not mandate any requirements for state, local, or tribal governments, nor will it affect private sector costs.

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

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

On August 3, 2010, CMS published a notice of proposed rulemaking in the *Federal Register*. 75 Fed. Reg. 46,169. CMS received approximately 774 timely pieces of correspondence from the public. CMS responded to the comments in the final rule. 75 Fed. Reg. 71,800.

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

The final rule contains information collection requirements under the Act. CMS solicited comments on the requirements in the proposed rule on August 3, 2010. The final rule contains requirements for the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) Quality Measures for the CY 2012 and CY 2013 payment determinations, which are currently approved under OCN: 0938-1109. For the CY 2012 payment determination, CMS estimates a total annual burden of 542,500 hours, and 553 annual burden hours for structural measure data. For the CY 2013 payment determinations, CMS estimates the annual burden associated with the submission requirements for the chart-abstracted data is 1,084,380 hours, and 1,066 annual burden hours for the structural measures.

The final rule with comment period also includes HOP QDRP Validation Requirements that CMS estimates will take the 800 sampled hospitals approximately 12 hours to comply with for an annual burden of 9,600 hours. These requirements are currently approved under OCN: 0938-1109.

Statutory authorization for the rule

The final rule with comment period 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 (Regulatory Planning and Review)

CMS determined that the final rule with comment period was economically significant, and it was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule with comment period will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have federalism implications.