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United States Government Accountability Office
Washington, DC 20548

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November 22, 2011

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies*

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; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies*" (RIN: 0938-AQ27). We received the rule on November 2, 2011. It was published in the *Federal Register* as a final rule on November 10, 2011. 76 Fed. Reg. 70,228.

The final rule updates and makes certain revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012. The final rule also finalizes the interim final rule with comment period published on April 6, 2011, regarding the transition budget-neutrality adjustment under the ESRD PPS. The final rule also sets forth requirements for the ESRD quality incentive program (QIP) for payment years (PYs) 2013 and 2014. In addition, the final rule revises the ambulance fee schedule regulations to conform to statutory changes.

The final rule, a major rule under the Congressional Review Act (CRA), has an announced effective date of January 1, 2012. 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, 2011, and it was not published in the *Federal Register* until November 10, 2011. 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 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

ENCLOSURE

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; END-STAGE RENAL DISEASE
PROSPECTIVE PAYMENT SYSTEM AND
QUALITY INCENTIVE PROGRAM; AMBULANCE FEE SCHEDULE;
DURABLE MEDICAL EQUIPMENT; AND
COMPETITIVE ACQUISITION OF CERTAIN DURABLE
MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES"
(RIN: 0938-AQ27)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. CMS estimates that the final revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) will result in an increase of approximately \$240 million in payments to ESRD facilities in calendar year (CY) 2012. Furthermore, as a result of implementing the ESRD Quality Incentive Program (QIP) for Medicare outpatient ESRD dialysis providers and facilities, CMS estimates aggregate payment reductions in payment years (PY) 2013 and 2014 would be \$23.7 million and \$22.1 million, respectively. However, given the lack of data for several measures, the actual impact of the PY 2014 ESRD QIP may vary significantly from the values provided. Lastly, the aggregate costs associated with the QIP collection of information requirements described in the final rule are estimated to be \$400,000 for all ESRD providers/facilities in PY 2013. The additional estimated aggregate costs associated with the other collection of information requirements in this final rule are expected to be approximately less than \$24 million for all participating ESRD facilities. CMS determined that the impact of section 106 of the Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309, requiring the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2011, is estimated to be \$20 million for CY 2011.

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

CMS determined that the final rule will not have a significant economic impact on a substantial number of small entities. CMS also determined that the final rule will not have a significant impact on a substantial number 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 does not include any mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of \$136 million.

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

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

CMS published a notice of proposed rulemaking in the *Federal Register* on July 8, 2011. 76 Fed. Reg. 40,498. CMS responded to comments on the proposed rule in the final rule. 76 Fed. Reg. 70,228.

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

The final rule contains information collection requirements under the Paperwork Reduction Act, which CMS finalized in the final rule. CMS estimates that for CY 2012, the total initial ESRD facility burden would be 67 hours, with an associated cost of \$1,044 for all facilities impacted by the requirement. CMS also describes associated information collection requirements which are not included in the final rule.

Statutory authorization for the rule

The final rule is authorized by section 1881(b)(14) of the Social Security Act, as amended.

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

CMS determined that the final rule is economically significant under the Order, and the rule has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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