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B-320410

August 24, 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 Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; End-Stage Renal Disease Prospective Payment System*

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” (RIN: 0938-AP57). We received the rule on July 30, 2010. It was published in the *Federal Register* as a final rule on August 12, 2010. 75 Fed. Reg. 49,030. The rule has a stated effective date of January 1, 2011, except for two specific provisions, one of which is effective November 1, 2010, and the other January 1, 2014.

The final rule implements a case-mix adjusted bundled prospective payment system for Medicare outpatient end-stage renal disease dialysis facilities, in compliance with the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 6, 153(b), 122 Stat. 2553. This rule also replaces the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient end-stage renal disease services.

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 rule.

Our review of the procedural steps taken indicates that 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"  
(RIN: 0938-AP57)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS's analysis shows an overall decrease in payments to all end-stage renal disease facilities for renal dialysis of 2 percent, or approximately \$200 million, from what the payments would have been in the absence of this rule in calendar year 2011.

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

CMS determined that this final rule will not have a significant economic impact on a substantial number of small entities. Further, CMS determined that this 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 this final rule does not include any mandate that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of \$133 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 proposed rule on September 29, 2009, with a comment period ending on November 16, 2009. 74 Fed. Reg. 49,922. On November 4, 2009, CMS published a notice extending the public comment period an additional 30 days to December 16, 2009. 74 Fed. Reg. 57,127. CMS received approximately 1,475 public comments, including comments resulting from a large write-in campaign regarding oral Part B drugs. Interested parties that submitted comments included numerous dialysis facilities, the national organizations representing dialysis facilities, nephrologists, and patients, the major chain facilities, clinical laboratories,

pharmaceutical manufacturers, hospitals and their representatives, individual dialysis patients, and MedPAC. CMS addressed the comments in the final rule.

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

CMS determined that this final rule contains information collection requirements under the Act and has submitted these requirements to the Office of Management and Budget (OMB) for review. CMS estimates that the first of two requirements will have 857 respondents providing 400 responses with a total annual burden of 33.2 hours. CMS estimates that the second requirement will have 4,951 respondents providing 2,120 responses for a total annual burden of 530 hours.

#### Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1302, 1395m, 1395hh, 1395ddd, and 1395rr of title 42, United State Code.

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

CMS determined that this final rule is “economically significant” because the estimated total payments for renal dialysis services in calendar year 2011 will equal 98 percent of the estimated total payments that would have been made if the final rule was not implemented, which equates to an approximate \$200 million decrease in payments to end-stage renal disease facilities. The rule was reviewed by OMB under the Order.

#### Executive Order No. 13,132 (Federalism)

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