GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-317643

January 16, 2009

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

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

The Honorable Charles B. Rangel
Chairman
The Honorable Dave Camp
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; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*

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; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" (RIN: 0938-AO84). We received the rule on January 2, 2009. It was published in the *Federal Register* as a final rule on January 2, 2009. 74 Fed. Reg. 166.

The final rule implements section 1834(a)(16) of the Social Security Act by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics, and supplies to furnish CMS with a surety bond. The final rule has an effective date of March 3, 2009.

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 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
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 AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; SURETY BOND REQUIREMENT FOR
SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS,
ORTHOTICS, AND SUPPLIES (DMEPOS)"
(RIN: 0938-AO84)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis of this final rule and estimates that the annual cost of the surety bond requirement will be $102.3 million. CMS expects the bond requirement to provide significant program integrity benefits for Medicare on the grounds that it will be able to recoup otherwise uncollectible overpayments.

(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 direct "significant economic impact on a substantial number of small entities" and was not required to prepare a regulatory flexibility analysis. Nonetheless, CMS recognized that the cost of a surety bond may impact smaller pharmacies, as well as small medical supply companies in rural areas, to a greater extent than large chain pharmacies. For this reason, CMS elected to prepare a voluntary Final Regulatory Flexibility Analysis. CMS stated that it incorporated several options designed to minimize the burden of the surety bond requirement on small entities; for example, in the final rule, CMS approved multiple accreditation organizations that serve smaller suppliers.

(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 contain mandates that will impose annual spending costs on state, local, or tribal governments, in the aggregate, or on the private sector, of $130 million or greater. (CMS estimates that the maximum annual cost of this final rule will be $102.3 million.)

(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. On August 1, 2007, CMS published a Notice of Proposed Rulemaking in the *Federal Register*. 72 Fed. Reg. 42,001. CMS received approximately 200 comments on the proposed rule and responds to the comments in the final rule. 74 Fed. Reg. 169.

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

The final rule contains new information collection requirements that have been submitted for review by the Office of Management and Budget (OMB) as required by the Act.

Statutory authorization for the rule

Consistent with section 4312(a) of the Balanced Budget Act of 1997, this final rule implements section 1834(a)(16) of the Social Security Act by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics, and supplies to furnish CMS with a surety bond.

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

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 concluded that this final rule does not have federalism implications; CMS determined that this final rule does not significantly affect the rights, roles, and responsibilities of the states.