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Washington, DC 20548

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B-309303

April 24, 2007

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; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*

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; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues” (RIN: 0938-AN14). We received the rule on April 6, 2007. It was published in the *Federal Register* as a final rule on April 10, 2007. 72 Fed. Reg. 17,992. The final rule is effective on June 11, 2007.

The final rule establishes competitive bidding programs for certain Medicare B covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and

(b) of the Social Security Act. The competitive bidding programs, which will be phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B.

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, please contact Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Robert J. Cramer  
Associate General Counsel

Enclosure

cc: Ann Stallion  
Regulations Coordinator  
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; COMPETITIVE ACQUISITION FOR  
CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS,  
ORTHOTICS, AND SUPPLIES (DMEPOS) AND OTHER ISSUES"  
(RIN: 0938-AN14)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis for this final rule. Much of the analysis was based on demonstration projects on DMEPOS competitive bidding programs.

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

CMS certified that the proposed rule would not have a significant economic impact on a substantial number of small entities. However, CMS prepared a Final Regulatory Flexibility Analysis in connection with the final rule, having concluded that the final rule will have a significant impact on a substantial number of small suppliers. The analysis complies with the requirements of the Act, including the steps taken to reduce the economic impact on small entities. For example, CMS revised the proposed rule to help small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program by including a target goal for small supplier's participation in each product category.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$120 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.*

The final rule was issued using the notice and comment procedures found at 5 U.S.C. § 553. On May 1, 2006, CMS published a Notice of Proposed Rulemaking in the *Federal Register*. 71 Fed. Reg. 25,654. The proposed rule established competitive bidding programs for certain covered items of durable medical equipment,

prosthetics, orthotics, and supplies, but also included other requirements, such as those pertaining to independent accreditation organizations that will apply quality standards to all DMEPOS suppliers. In response CMS received approximately 2,120 comments. CMS decided to issue the proposed rule as several separate rules; for example, CMS published a final rule on August 18, 2006, relating to the accreditation of DMEPOS supplies. 71 Fed. Reg. 48,354. In this final rule, CMS responded to the comments pertaining to the competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics and supplies and other issues. 72 Fed. Reg. 17,992.

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

The final rule contains information collections within the framework of the Paperwork Reduction Act. CMS has requested public comments on the paperwork burden which are due by November 30, 2007. The OMB control number is 0938-0717.

Statutory authorization for the rule

The final rule is promulgated under the authority found at sections 1847(a) and (b) of the Social Security Act as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173.

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

CMS determined that the final rule does not have sufficient federalism implications to require the preparation of a federalism impact statement.