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B-297738

December 21, 2005

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

The Honorable Joe Barton  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable William M. Thomas  
Chairman  
The Honorable Charles B. Rangel  
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; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services)*

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; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services)” (RIN: 0938-AN81). We received the rule on December 13, 2005. It was published in the Federal Register as a final rule on December 13, 2005. 70 Fed. Reg. 73623.

The rule finalizes the process for establishing a realistic and equitable payment amount for Medicare Part B services (other than physicians’ services) when the existing payment amounts are inherently unreasonable because they are grossly

excessive or grossly deficient. The process does not apply to services paid under a prospective payment system such as outpatient hospital services or home health 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 indicates that CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. 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

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: Ann Stallion  
Regulations Coordinator  
Department of Health and  
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
ENTITLED  
"MEDICARE PROGRAM; APPLICATION OF INHERENT REASONABLENESS  
PAYMENT POLICY TO MEDICARE PART B SERVICES  
(OTHER THAN PHYSICIAN SERVICES)"  
(RIN: 0938-AN81)

(i) Cost-benefit analysis

CMS states that it lacks sufficient data to conduct a quantitative analysis of the impact of the rule. However, CMS believes the savings will be significant based on a June 2002 Office of the Inspector General report that indicated that Medicare may be overpaying between \$160 million and \$958 million per year for 16 items of medical equipment. Also, CMS relies on a July 2000 report by our Office that stated that Medicare may be overpaying for medical equipment by more than 20 percent (*Medicare Payments: Use of Revised "Inherent Reasonableness" Generally Appropriate*, GAO/HEHS-00-79).

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

For the reasons stated above, CMS does not have sufficient data to prepare a Regulatory Flexibility Analysis. However, when the process is implemented and the impact is seen on small entities, CMS will prepare the required analysis under the Act.

(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 \$110 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 December 13, 2002, CMS published an interim final rule in the Federal Register. 67 Fed. Reg. 76684. CMS received 189 timely comments in response to the publication and discusses the comments in the preamble to the final rule.

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

The final rule does not contain any information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule was promulgated under the authority found in section 1842(b)(8) of the Social Security Act, as amended by section 4316 of the Balanced Budget Act of 1997 (Pub. L. 105-33).

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 states that the final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact statement.