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United States General Accounting Office  
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B-291770

December 23, 2002

The Honorable Max Baucus  
Chairman  
The Honorable Chuck Grassley  
Ranking Minority Member  
Committee on Finance  
United States Senate

The Honorable W.J. "Billy" Tauzin  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Bill 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, Center for Medicare and Medicaid Services: Medicare Program; Application of Inherent Reasonableness to All 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, Center for Medicare and Medicaid Services (CMS), entitled "Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services (Other Than Physician Services)" (RIN: 0938-AJ97). We received the rule on December 12, 2002. It was published in the Federal Register as an interim final rule on December 13, 2002. 67 Fed. Reg. 76684.

The interim final rule sets forth the process for establishing a realistic and equitable payment amount for all Medicare Part B services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient.

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 the 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 William Scanlon, Managing Director, Health Care. Mr. Scanlon can be reached at (202) 512-7114.

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,  
CENTER FOR MEDICARE AND MEDICAID SERVICES  
ENTITLED  
"MEDICARE PROGRAM; APPLICATION OF  
INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES  
(OTHER THAN PHYSICIAN SERVICES)"  
(RIN: 0938-AJ97)

(i) Cost-benefit analysis

CMS states that the interim final rule does not include any actual inherent reasonableness determinations and, therefore, has no immediate impact on Medicare payment amounts. The rule does establish a process for making such determinations. However, CMS does not have sufficient data to conduct a quantitative analysis of the interim final rule. CMS believes that the future use of inherent reasonableness has the potential to have significant impact.

This possible impact has been shown by a CMS Office of the Inspector General report issued in June 2002, which indicated that Medicare might be overpaying between \$130 million and \$958 million per year for 16 items of medical equipment. Also, a General Accounting Office report entitled "*Medical Payments—Use of Revised 'Inherent Reasonableness' Generally Appropriate*" (GAO/HEHS-00-79) found that Medicare might be overpaying for medical equipment by more than 20 percent.

When CMS has sufficient data, it will prepare the required impact statements under Executive Order 12866 and publish it in the Federal Register.

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

Based on the above reasoning, CMS states it does not have sufficient data to determine the impact of the interim final rule on small entities. As noted above, when CMS has sufficient data it will make the required determinations under the Regulatory Flexibility Act and publish the analysis in the Federal Register.

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

As defined in title II, the interim final rule does not contain either an intergovernmental or private sector mandate of more than \$100 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.

In section 223 of the Balanced Budget Refinement Act of 1999, CMS is prohibited from using the inherent reasonableness authority until it has responded to the GAO report and publishes a final rulemaking that responds to the comments it received on an interim final rule published on January 7, 1998 (63 Fed. Reg. 687). In the preamble to the instant rule, CMS responds to the comments it received in response to the prior rulemaking.

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

The interim 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 interim final rule is promulgated under the authority contained in sections 1102, 1842(b)(8), 1842(b)(9), and 1871 of the Social Security Act.

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

The interim rule does not contain sufficient federalism implications to warrant the preparation of a Federalism Assessment.