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United States General Accounting Office
Washington, DC 20548

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January 15, 2004

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
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 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; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004*

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; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004" (RIN: 0938-AM97). We received the rule on December 31, 2003. It was published in the Federal Register as an "interim final rule with comment period" on January 7, 2004. 69 Fed. Reg. 1084.

The interim final rule implements the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that are applicable in 2004 to Medicare payment for covered drugs and physician fee schedule services. These provisions (1) revise the current payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis, (2) make changes to

Medicare payment for furnishing or administering drugs and biologicals, (3) revise the geographic practice cost indices, and (4) change the physician fee schedule conversion factor.

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,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; CHANGES TO MEDICARE PAYMENT FOR
DRUGS AND PHYSICIAN FEE SCHEDULE PAYMENTS
FOR CALENDAR YEAR 2004"
(RIN: 0938-AM97)

(i) Cost-benefit analysis

CMS estimates that the changes contained in the interim final rule regarding the physician fee schedule and drug payment rates to increase Medicare spending by more than \$1.0 billion in fiscal year 2004.

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

CMS prepared a Final Regulatory Flexibility Analysis in accordance with the statute and discusses the impact on various medical specialties. CMS notes that it had very little opportunity to utilize alternatives because most of the changes were mandated by 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 interim final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, 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.

CMS has found "good cause" to waive the notice and comment procedures and the 30-day delay in a rule's effective date required by 5 U.S.C. 553. The Act requires the new physician fee schedule and drug payment rates to be implemented by January 1, 2004. However, CMS is accepting comments until March 8, 2004.

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

The interim final rule contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

The collection requires a manufacturer requesting a drug payment exception to the default 85 percent used in the general rule to submit data and information including the manufacturer's average sales price for the drug. CMS expects the total burden of this collection to be 4,500 hours.

Statutory authorization for the rule

The interim final rule is promulgated under the authority contained in sections 1102, 1802, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395a, 1395hh, and 1395rr(b)(1)).

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an "economically significant" regulatory action.

Executive Order No. 13132 (Federalism)

The interim final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact analysis.