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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; Hospital Outpatient Prospective Payment System; Payment Reform 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; Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004" (RIN: 0938-AM96). 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 6, 2004. 69 Fed. Reg. 820.

The interim final rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that affect the Medicare outpatient prospective payment system. The provisions, among other items, alter the methods for drug payment in hospital outpatient departments and affect the methodology for

paying for pass-through and non-pass-through drugs under the outpatient prospective payment system.

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; HOSPITAL OUTPATIENT
PROSPECTIVE PAYMENT SYSTEM;
PAYMENT REFORM FOR CALENDAR YEAR 2004
(RIN: 0938-AM96)

(i) Cost-benefit analysis

CMS's Office of the Actuary estimates that the total change in expenditures under the outpatient prospective payment system for calendar year 2004 as a result of this rule will be approximately \$150 million.

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

As the interim final rule was not preceded by a notice of proposed rulemaking, the requirements of the Regulatory Flexibility Act do not apply.

(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 will not impose 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 Secretary of Health and Human Services has found good cause to waive the notice and comment procedures and the 30-day delay in effective date requirement found at 5 U.S.C. 553. The Secretary has found that it is not in the public interest to delay the implementation of these changes past the statutory effective date of January 1, 2004, because it would cause a delay in payment increases for many drugs and biomedical and brachytherapy sources.

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 found in sections 303, 411, and 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).

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