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United States Government Accountability Office
Washington, DC 20548

B-295860

February 11, 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; Medicare Prescription Drug Benefit*

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; Medicare Prescription Drug Benefit" (RIN: 0938-AN08). We received the rule on January 21, 2005. It was published in the Federal Register as a final rule on January 28, 2005. 70 Fed. Reg. 4194.

The final rule implements provisions of the Social Security Act added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) establishing the new voluntary prescription drug benefit program.

The final rule has an announced effective date of March 22, 2005. The Congressional Review Act requires a 60-day delay in the effective date of a major rule from the date of publication in the Federal Register or receipt of the rule by Congress, whichever is

later. 5 U.S.C. 801(a)(3)(A). The rule was received by Congress on January 21, 2005, but was not published in the Federal Register until January 28, 2005. Therefore, the final rule does not have the required 60-day delay in its effective date. While we recognize that the rule was on display at the Federal Register from January 21, 2005, section 801(a)(3)(A) requires publication in the Register for the start of the 60-day period.

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, with the exception of the 60-day delay in the rule's effective date, 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; MEDICARE PRESCRIPTION DRUG BENEFIT"
(RIN: 0938-AN08)

(i) Cost-benefit analysis

CMS expects the Medicare drug benefit to increase federal spending on Medicare benefits and decrease federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). CMS's costs analysis, contained in the rule's preamble, estimates Medicare spending will increase by nearly \$61 billion in calendar year (CY) 2006 and by \$365 billion from CY 2006-2010. The reduction in Medicaid spending will be about \$11 billion in CY 2006 and \$72 billion between CY 2006-2010. The net effect of the rule is about \$49 billion in CY 2006 and \$68 billion in CY 2010 with the total net increase from CY 2006-2010 being \$293 billion.

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

CMS states that while it believes that it could properly certify that the final rule will not have a significant economic impact on a substantial number of small entities, including small retail pharmacies, employers, or insurers, CMS has prepared a Final Regulatory Flexibility Analysis for each. The analysis complies with the requirements of the Act.

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

CMS states that 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. While CMS recognizes that the rule will impose costs on both the private sector and states, CMS states that the costs will not exceed the \$110 million threshold.

(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 August 3, 2004, CMS published a Notice of Proposed Rulemaking in the Federal Register. 69 Fed. Reg. 46631. In response, CMS received 7,696 items of

correspondence containing comments on the proposed rule. These comments are discussed in the preamble to the final rule.

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

The final rule contains numerous information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The preamble to the final rule contains the information required by the Act, including the burden hours for each collection.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority found in section 101 of title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 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)

The final rule, in implementing the provisions of the MMA, contains numerous preemptions of state law, including state regulation of prescription drug plans and the establishment of a federal grievance procedure which preempts state grievance procedures. CMS has met and consulted with numerous state officials and continues these consultations with the convening of the State Issue Workshop.