GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-309802

August 1, 2007

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

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

The Honorable Charles B. Rangel
Chairman
The Honorable Jim McCrery
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicaid Program; Prescription Drugs*

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 "Medicaid Program; Prescription Drugs" (RIN: 0938-AO20). We received the rule on July 9, 2007. It was published in the *Federal Register* as a final rule with comment period on July 17, 2007. 72 Fed. Reg. 39,142. The final rule has an effective date of October 1, 2007.

The final rule implements provisions of the Deficit Reduction Act (DRA)[1] pertaining to prescription drugs under the Medicaid Program. More specifically, under the Medicaid program, states may provide coverage of certain outpatient drugs and the

[1] Pub. L. No. 109-171, Feb. 8, 2006.

final rule specifies certain requirements for federal financial participation in such state expenditures. In order for payment to be made available, drug manufacturers must enter into the national rebate agreement as set forth in section 1927 of the Social Security Act (the Medicaid Drug Rebate Program). The final rule implements changes to the Medicaid Drug Rebate Program required by the DRA. The DRA requires CMS to promulgate the final rule no later than July 1, 2007.

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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. 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) 512-7114.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

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

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICAID PROGRAM; PRESCRIPTION DRUGS"
(RIN: 0938-AO20)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule. CMS estimates that this final rule will save $8.4 billion over the next 5 years ($4.93 billion federal savings and $3.52 billion state savings). This figure represents a 5.6 percent reduction in total Medicaid drug expenditures in federal fiscal years 2007-2011. None of the estimates include federal or state administrative costs. CMS contends that these administrative costs will be small because they involve changes in work processes rather than new activities.

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

CMS estimated that the final rule will have a significant economic effect on small businesses, including small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid. CMS prepared a Final Regulatory Analysis for the final rule that complies with the requirements of the Act; for example, CMS considered alternatives that would reduce the impact on small businesses.

(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 $120 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 promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. CMS published a proposed rule in the *Federal Register* on December 22, 2006. 71 Fed. Reg. 77,174. CMS published the final rule with comment period in the *Federal Register* on July 17, 2007, which

focuses primarily on the provisions of the Deficit Reduction Act that address the Medicaid Drug Rebate Program. In the final rule, CMS stated it received over 1,600 timely comments and addressed the relevant comments to the proposed rule.

As background, CMS published a proposed rule on September 19, 1995. 60 Fed. Reg. 48,442. The proposed rule pertained to the Medicaid Drug Rebate Program and addressed the national rebate agreement. 56 Fed. Reg. 7049 (Feb. 21, 1991). On August 29, 2003, CMS finalized two of the provisions in the proposed rule through a final rule with comment period. 68 Fed. Reg. 51,912. On November 26, 2004, CMS finalized another provision of the proposed rule. 69 Fed. Reg. 68,815. CMS published the final rule with comment period as a result of provisions in the DRA that address the Medicaid Drug Rebate Program. CMS states that the final rule will "bring together existing and new regulatory requirements in one, cohesive subpart."

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

The final rule contains information collections within the framework of the Paperwork Reduction Act. CMS published a notice requesting comments on the collection of information requirements accompanying the proposed rule and submitted requests to the Office of Management and Budget (OMB) in accordance with the Act, which were approved by OMB. Some of the revisions to the proposed rule affect the collections of information. Therefore, CMS has requested public comments on the paperwork burden with respect to these revisions, which are due by January 2, 2008.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority found in sections 6001(a)–(d), 6002, and 6003 of the Deficit Reduction Act (DRA), Pub. L. No. 109-171 (Feb. 8, 2006). It also implements certain parts of sections 1927 and 1903 of the Social Security Act that pertain to requirements under the Medicaid Drug Rebate Program as revised by the DRA.

Executive Order No. 12,866

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

Executive Order No. 13,132 (Federalism)

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