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United States General Accounting Office  
Washington, DC 20548

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B-292824

September 15, 2003

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

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program*

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; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program" (RIN: 0938-AM20). We received the rule on September 4, 2003. It was published in the Federal Register as a final rule on August 29, 2003. 68 Fed. Reg. 51912.

The final rule establishes new recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program and sets a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to CMS.

The final rule has an announced effective date of October 1, 2003. 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). As noted above, the rule was published on August 29, 2003, and was received by Congress on September 4, 2003. Therefore, the rule does not have the required delay in its effective date.

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 effective date, 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

ENCLOSURE

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  
"MEDICAID PROGRAM; TIME LIMITATION ON PRICE RECALCULATIONS AND  
RECORDKEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM"  
(RIN: 0938-AM20)

(i) Cost-benefit analysis

CMS estimates that the final rule will save \$90 million annually over the next 5 years (\$50 million in federal savings and \$40 million in state savings).

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

CMS has certified that the final rule will not have a significant economic impact on a substantial number of small entities.

(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 \$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 final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On September 19, 1995, a Notice of Proposed Rulemaking was published in the Federal Register. 60 Fed. Reg. 48442. In response to the proposal, 19 comments were received and the comments pertaining to the provisions of the final rule are discussed in the preamble.

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

The information collection requirements of the final rule have already been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0938-0578.

Statutory authorization for the rule

The final rule is promulgated under the authority contained in section 1102 of the Social Security Act (42 U.S.C. 1302).

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 does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.