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United States General Accounting Office  
Washington, DC 20548

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B-291233

September 17, 2002

The Honorable Max Baucus  
Chairman  
The Honorable Chuck Grassley  
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; Medicare-Endorsed Prescription Drug Card Assistance Initiative

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-Endorsed Prescription Drug Card Assistance Initiative" (RIN: 0938-AL25). We received the rule on August 30, 2002. It was published in the Federal Register as a final rule on September 4, 2002. 67 Fed. Reg. 56618.

The final rule describes CMS's Medicare-Endorsed Prescription Drug Card Assistance Initiative and sets forth the necessary requirements for card sponsors to participate in the initiative.

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.

For your information, on December 5, 2001, our Office issued a report entitled "Prescription Drugs: Prices Available Through Discount Cards and From Other Sources." (GAO-02-280R)

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; MEDICARE-ENDORSED PRESCRIPTION  
DRUG CARD ASSISTANCE INITIATIVE"  
(RIN: 0938-AL25)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services estimates that the savings to beneficiaries under the initiative will represent a total economic impact ranging from \$1.214 billion to \$1.619 billion in 2004, the first full year of operation. In 2005, the total estimated savings to beneficiaries would range from \$1.364 billion to \$1.819 billion. In 2008 (the fifth year of the estimate period), the total estimated savings would range from \$1.907 billion to \$2.542 billion. CMS states that the ultimate impact of the initiative will depend on the final designs of the card sponsors' programs.

(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. Therefore, CMS was not required to perform a Regulatory Flexibility Analysis (RFA) under the Act. However, CMS, in the preamble to the final rule, discusses the items normally included in an RFA, such as the number of small entities affected and a description of the alternatives considered.

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

According to CMS, the final rule does not contain an intergovernmental mandate, as defined in title II. While the rule will have an impact on the private sector, CMS does not expect the direct costs or outlays to exceed the Unfunded Mandates Reform Act's threshold of \$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 March 6, 2002, CMS published a Notice of Proposed Rulemaking in the

Federal Register. 67 Fed. Reg. 10262. The comments received in response to the notice are discussed in the preamble to the final rule.

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

The final rule contains information collections that, according to CMS, may be subject to review by the Office of Management and Budget under the Paperwork Reduction Act. In the preamble to the final rule, CMS discusses the information collections, the burdens the collections would impose, and the reasons CMS finds the collections may be exempt from the Act.

Statutory authorization for the rule

CMS states that the issuance of the final rule is primarily based on the authority contained in section 4359 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508). In addition, CMS cites sections 1102, 1140, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-10, and 1395hh).

Executive Order No. 12866

The final rule was reviewed by the Office of Management and Budget and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

CMS states that the final rule will impose no direct costs on state and local governments, will not preempt state law, or have any federalism implications. If states choose to partner with private card sponsors by selecting a Medicare-endorsed drug card program and offering state endorsement as well, it is a voluntary opportunity and has no federalism implications.