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December 22, 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

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: Medicare Program; Medicare Prescription Drug Discount Card*

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 (CMS), entitled "Medicare Program; Medicare Prescription Drug Discount Card" (RIN: 0938-AM71). We received the rule on December 15, 2003. It was published in the Federal Register as an "interim final rule with comment period" on December 15, 2003. 68 Fed. Reg. 69840.

The interim final rule provides for a voluntary prescription drug discount card program for Medicare beneficiaries entitled to benefits or enrolled under Part A or enrolled under Part B, excluding beneficiaries entitled to medical assistance for outpatient prescription drugs under Medicaid, including section 1115 waiver demonstrations.

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
ENTITLED
"MEDICARE PROGRAM; MEDICARE PRESCRIPTION
DRUG DISCOUNT CARD"
(RIN: 0938-AM71)

(i) Cost-benefit analysis

CMS estimates that savings for beneficiaries from discount card activities will range from \$1.4 billion to \$1.8 billion in the last nine months of 2004, \$2.0 billion to \$2.7 billion in 2005, and \$0.4 billion to \$0.6 billion in the transition period in 2006. Also, the subset of enrolled beneficiaries (an estimated 4.7 million) who qualify for transitional assistance are estimated to save an additional \$2.4 billion in last nine months of 2004, \$2.6 billion in 2005, and \$0.1 billion in 2006 (first four and one-half months) from the annual \$600 transitional assistance.

CMS also estimates the impact on the Medicare program spending will be increases of \$2.5 billion in calendar year 2004, \$2.7 billion in 2005, and \$0.1 billion in 2006 due to the transitional assistance. The vast majority of the spending is for the \$600 transitional assistance (\$2.4 billion in 2004, \$2.6 billion in 2005, and \$0.1 billion in 2006), with the remaining spending, \$0.14 billion in 2004 and 2005, for payment of the enrollment fee for transitional assistance eligible beneficiaries. In addition, CMS estimates that the administrative expenses to implement the program will be \$134 million.

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

Following its preparation of a Final Regulatory Flexibility Analysis, CMS has concluded that the interim 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

CMS states that 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized CMS to issue an interim final rule and make the rule effective upon publication rather than utilizing a notice of proposed rulemaking and receiving public comments. However, CMS is accepting comments on the interim final rule until January 14, 2004.

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

Section 105(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 exempts the Medicare drug discount card program from the requirements of the Paperwork Reduction Act, including the public comment and federal clearance requirements.

Statutory authorization for the rule

The interim final rule is promulgated under the authority contained in section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-391) (codified in section 1860D-31 of the Social Security Act).

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

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