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United States Government Accountability Office
Washington, DC 20548

B-295861

February 9, 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; Establishment of the Medicare Advantage 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 “Medicare Program; Establishment of the Medicare Advantage Program” (RIN: 0938-AN06). 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. 4588.

The final rule implements provisions of the Social Security Act establishing and regulating the Medicare Advantage (MA) program. The MA program replaces the Medicare+Choice program and attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries.

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; ESTABLISHMENT OF THE
MEDICARE ADVANTAGE PROGRAM"
(RIN: 0938-AN06)

(i) Cost-benefit analysis

CMS performed a regulatory impact analysis which concludes that the cost of the benefits to beneficiaries and medical plans which result from the final rule will be \$18.3 billion for the period 2004 to 2009.

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

CMS prepared a Final Regulatory Flexibility Analysis in connection with the final rule, which concludes that the 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 \$100 million (adjusted for inflation and currently about \$110 million) in any one year. However, CMS recognizes that there will be an indirect effect on state premium tax revenues due to increased enrollment in Medicare Advantage plans and reduced enrollment in certain Medigap policies.

(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. 46866. CMS received 186 items of correspondence containing more than a thousand specific comments on the proposed rule. The comments 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 are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. These collections include requirements that have already been approved (OMB No. 0938-0753), collections that have been modified but the burden hours are unaffected, and new collections. CMS has submitted the required information to OMB and requests public comment on the collections.

Statutory authorization for the rule

The final rule is promulgated under the authority found in Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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)

CMS finds that because of the implications for the states of federal preemption of state laws under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS will consult with the states regarding the role the states will play with respect to the regulation of Medicare plans. The consultation will also consider the effect on state agencies and beneficiaries enrolled in Medicare health plans.