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January 27, 2009

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

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Charles B. Rangel
Chairman
The Honorable Dave Camp
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 Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions*

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 Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions” (RIN: 0938-AP24). We received the rule on January 7, 2009. It was published in the *Federal Register* as a final rule with comment period on January 12, 2009. 74 Fed. Reg. 1494.

The final rule revises the regulations governing the Medicare Advantage program (Part C) and prescription drug benefit program (Part D). The final rule includes provisions regarding medical savings account plans, cost-sharing for dual eligible enrollees enrolled in the Medicare Advantage program, the prescription drug

payment and novation processes in the Part D program, and the enrollment and appeals processes for both programs. Also, the interim final rule with comment period relates to certain aspects of the Retiree Drug Subsidy Program and reflects the new statutory definitions relating to Special Needs Plans under Part C.

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 or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
Department of Health and
Human Services

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
"MEDICARE PROGRAM; MEDICARE ADVANTAGE AND
PRESCRIPTION DRUG BENEFIT PROGRAMS:
NEGOTIATED PRICING AND REMAINING REVISIONS"
(RIN: 0938-AP24)

(i) Cost-benefit analysis

CMS estimates that the costs associated with revisions to the beneficiary cost sharing and reinsurance subsidy payments will be \$30 million in fiscal year (FY) 2010, with a total cost of \$530 million in FYs 2010-2018. CMS estimates that the costs related to other provisions in the final rule will be approximately \$4,381,800 in FY 2010 and \$3,821,643 per year in FYs 2011-2018. CMS states that it has no reliable basis for estimating the economic benefits of the final rule, but expects that the clarifications included in the final rule could contribute to greater plan efficiency and compliance with program regulations.

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

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

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

CMS determined that the final rule does not contain mandates that will impose spending costs on state, local, or tribal governments, in the aggregate, or on the private sector of \$130 million.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

CMS published a proposed rule in the *Federal Register* on May 16, 2008. 73 Fed. Reg. 28,556. After the proposed rule was published, on July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted. Pub. L. 110-275.

MIPPA included a number of provisions that addressed the same requirements addressed in the proposed rule, some of which paralleled the proposed requirements and others that complemented or superseded the proposed requirements. CMS received over 100 comments on the proposed rule and responded to those comments in the final rule, while also taking into account statutory revisions contained in MIPPA. 74 Fed. Reg. 1494.

CMS waived notice-and-comment rulemaking procedures with respect to the provisions of the final rule adding definitions relating to the special needs plan. CMS found that it would be unnecessary and contrary to the public interest to seek prior public comment on those provisions. Instead, CMS issued the provisions on an interim basis and is providing a 60-day public comment period.

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

CMS solicited additional public comments on the information collection requirements contained in the final rule and will subsequently submit the final rule to the Office of Management and Budget (OMB) for review and approval.

Statutory authorization for the rule

The final rule is authorized by sections 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act. 42 U.S.C. §§ 1302, 1395w-101 through 1395w-152, and 1395hh.

Executive Order No. 12,866 (Regulatory Planning and Review)

The final rule was reviewed by the Office of Management and Budget in accordance with the provisions of the Executive Order. Because the final rule will have economically significant effects, CMS prepared a regulatory impact analysis for the rule.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule will not have a substantial direct effect on state or local governments, preempt states, or otherwise have federalism implications.