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B-322415

September 16, 2011

The Honorable Max Baucus  
Chairman  
The Honorable Orrin G. Hatch  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Dave Camp  
Chairman  
The Honorable Sander M. Levin  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs*

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 & Medicaid Services (CMS), entitled “Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs” (RINs: 0938-AP24, 0938-AP52). We received the rule on September 1, 2011. It was published in the *Federal Register* as a final rule on September 1, 2011, with a stated effective date of October 31, 2011. 76 Fed. Reg. 54,600.

This final rule finalizes revisions to the regulations governing the Medicare Advantage (MA) program (Part C), prescription drug benefit program (Part D) and section 1876 cost plans, including implementing statutory requirements regarding

special needs plans, private fee-for-service plans, regional preferred provider organizations plans. This final rule also revised the regulations governing Medicare medical savings accounts plans; cost-sharing for dual-eligible enrollees in the MA program; prescription drug pricing, coverage, and payment processes in the Part D program; and requirements governing the marketing of Part C and Part D plans. These changes clarify various program participation requirements, strengthen beneficiary protections, strengthen CMS's ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers, and make other clarifications and technical changes.

Enclosed is our assessment of 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 of the procedural steps taken 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  
Managing 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 & MEDICAID SERVICES  
ENTITLED  
"MEDICARE PROGRAM; MEDICARE ADVANTAGE  
AND PRESCRIPTION DRUG BENEFIT PROGRAMS"  
(RINS: 0938-AP24, 0938-AP52)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule for fiscal years 2010 through 2015. CMS expects an aggregate net savings to the federal government of approximately \$520 million for fiscal years (FYs) 2010 through 2015 as a result of the provisions in this final rule. According to CMS, this estimate represents \$1.02 billion in savings to the federal government—a result of the requirement that certain non-employer and all employer private-fee-for-service plans establish contracts with providers. CMS's net savings estimate also includes costs of approximately \$500 million from the implementation of prompt payment by prescription drug plans and Medicare Advantage prescription drug plans from FYs 2010 through 2015. CMS estimates that administrative costs associated with the provisions of this final rule add negligibly to the total administrative costs of the Medicare Advantage or Part D programs.

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

CMS determined that this final rule will have a significant impact on a substantial number of small entities, such as the cost of the prompt payment provision to small retail pharmacies and pharmacy benefit managers. CMS analyzed the provision's impact on small entities in its interim final rule with comment period. 73 Fed. Reg. 54,226 (Sept. 18, 2008).

(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 this final rule does not mandate any spending by state, local, or tribal governments, in the aggregate, or by the private sector of \$100 million (\$136 million adjusted for inflation) 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.

CMS promulgated interim final rules for comment on September 18, 2008, and November 14, 2008. 73 Fed. Reg. 54,226; 73 Fed. Reg. 67,406. This rule finalizes certain parts of those interim final rules. CMS addressed comments made on the interim final rules in this final rule.

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

CMS determined that this final rule contains information collection requirements under the Act. CMS identified 10 different regulatory sections imposing recordkeeping burdens with a total of 2,141 respondents and 111,172 total annual burden hours, for a total cost of \$8,762,666.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of section 9701 of title 31, United States Code and sections 300e, 300e-5, 300e-9, 1102, 1302, 1395w-101 through 1395w-152, 1395hh, 1860D-1 through 1860D-42, and 1871 of title 42, United States Code.

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

CMS determined that this final rule is economically significant under the Order and the rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that because this final rule does not impose any costs on state or local governments, the requirements of the Order are not applicable.