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Washington, DC 20548

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April 25, 2012

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 Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander 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; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes*

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 “Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes” (RIN: 0938-AQ86). We received the rule on April 2, 2012. It was published in the *Federal Register* as a final rule with comment period on April 12, 2012. 77 Fed. Reg. 22,072.

This final rule with comment period revises the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement new statutory requirements, strengthen beneficiary protections, exclude

plan participants that perform poorly, improve program efficiencies, and clarify program requirements. It also responds to public comments regarding the long-term care facility conditions of participation pertaining to pharmacy services.

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: Annie Lamb
Regulations Coordinator
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
"CHANGES TO THE MEDICARE ADVANTAGE AND THE
MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS FOR
CONTRACT YEAR 2013 AND OTHER CHANGES"
(RIN: 0938-AQ86)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) discussed the costs and benefits of this final rule with comment period. CMS estimates that the aggregate costs to the health care sector for fiscal years 2013 through 2018 will be \$31,249.28 million. CMS estimates that the savings to the federal government over the same time period will be \$1,260.78 million. CMS also estimates that the costs to Medicare Advantage organizations and Part D sponsors from 2013 to 2018 will be \$193.19 million, costs to manufacturers will be \$29,797.82 million, and costs to states (negative savings) will be \$2.62 million. With regard to benefits, CMS believes that a well-implemented Discount Program will increase beneficiary adherence to medication regimens. CMS also states that the audit and dispute programs will both contribute to the stable operation of the Discount Program. Among other things, CMS also states that CMS's ability to terminate the agreement upon extreme noncompliance by manufacturers will likely encourage manufacturers to address issues quickly.

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

CMS determined that this final rule with comment period will not have a significant impact on a substantial number of small entities. In addition, CMS determined that this final rule will not have a significant impact 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 this final rule with comment period will require spending during at least one year by state, local, or tribal governments in aggregate, or by the private sector of \$100 million (\$136 million adjusted for inflation).

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

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

On October 11, 2011, CMS published a proposed rule. 76 Fed. Reg. 63,018. CMS received approximately 516 items of timely correspondence containing comments on the proposed rule. Commenters included health and drug plan organizations, insurance industry trade groups, provider associations, pharmacists (including consultant pharmacists) and pharmacy associations, representatives of hospital and long term care institutions, pharmacy benefit managers, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, private citizens, ombudsmen, and others.

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

CMS determined that this final rule with comment period contains information collection requirements under the Act. CMS estimates that the fiscal year reporting, recordkeeping, and cost burdens associated with the information collection requirements will be \$1,583,646.

Statutory authorization for the rule

CMS promulgated this final rule with comment period under the authority of section 9701 of title 31 and sections 300e, 300e-5, 300e-9, 1302, 1395w-101 through 1395w-153, and 1395hh of title 42, United States Code.

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

CMS determined that this final rule with comment period is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule with comment period will not impose significant direct requirement costs on state and local governments, will not preempt state law, and does not otherwise has federalism implications under the Order.