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February 16, 2016

The Honorable Orrin G. Hatch  
Chairman  
The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Kevin Brady  
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: Medicaid Program; Covered Outpatient Drugs*

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 “Medicaid Program; Covered Outpatient Drugs” (RIN: 0938-AQ41). We received the rule on January 27, 2016. It was published in the *Federal Register* as a final rule with comment period February 1, 2016. 81 Fed. Reg. 5170.

The final rule implements provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). This final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program.

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  
Deputy Director, ODRM  
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  
"MEDICAID PROGRAM; COVERED OUTPATIENT DRUGS"  
(RIN: 0938-AQ41)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. With respect to annualized monetary transfers associated with this rule, CMS estimates used a 7 percent discount rate to produce a reduction of transfers from the federal government to the states of \$316.9 million, a reduction in transfers from state governments to retail pharmacies less increased transfers from drug manufacturers to state governments to net \$221.5 million, and costs to drug manufacturers and states of \$94.9 million. Using a 3 percent discount rate, these estimates are \$319.8 million, \$223.5 million, and \$90 million, respectively. CMS also estimates that the savings from the implementation of the federal upper limits as revised in this final rule will be \$2.735 billion over 5 years (2016 through 2020), \$1.61 billion to the federal government, and \$1.125 billion to the states. Lastly, CMS estimates costs will be \$431.96 million to drug manufacturers and states for federal fiscal years 2016 through 2020.

(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 will have a significant economic impact on a substantial number of small entities. CMS performed a Regulatory Impact Analysis which included a statement of need, a summary of overall impacts, an economic analysis, and a description of alternatives considered.

(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 imposes no mandate on drug manufacturers and other private entities. CMS also determined the rule will not impose additional mandates on states and local governments. CMS found, however, that this final rule does have tribal implications. CMS stated that it obtained the advice and input of tribal officials during the Tribal Technical Advisory Group meeting on February 23, 2012, and consulted with tribal officials during an All Tribes' Call on March 16, 2012.

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

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

On February 2, 2012, CMS published a proposed rule. 77 Fed. Reg. 5318. CMS received approximately 425 comments from drug manufacturers, membership organizations, law firms, pharmacy benefit managers, state Medicaid agencies, advocacy groups, not-for-profit

organizations, consulting firms, health care providers, employers, health insurers, health care associations, as well as individual citizens. CMS responded to comments in the final rule.

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

CMS determined that this final rule contains information collection requirements under the Act. CMS's descriptions and Office of Management and Budget (OMB) control numbers for these information collection requirements are 5i Determination (0938-0578), Line Extension Determination (0938-0578), Line Extension Reporting (0938-0578), AMP/BP Reconfiguring Pricing System (0938-0578), AMP/BP Training/Start-up Costs (0938-0578), and the states' burden to implement new reimbursement requirements (0938-1148). CMS estimates these requirements will have a total annual burden of 3,473,060 hours, a total labor cost of reporting of \$95,289,343, and total capital and maintenance costs of \$234,669,440, resulting in a total cost of \$329,958,783.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of section 1102 of the Social Security Act. 42 U.S.C. § 1302.

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

CMS determined that this final rule is economically significant under the Order. The rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise have federalism implications.