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November 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 Shared Savings Program: Accountable Care Organizations*

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 Shared Savings Program: Accountable Care Organizations" (RIN: 0938-AQ22). We received the rule on November 2, 2011. It was published in the *Federal Register* as a final rule on November 2, 2011, with a stated effective date of January 3, 2012. 76 Fed. Reg. 67,802.

The final rule implements section 3022 of the Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 395-399 (Mar. 23, 2010). Section 3022 created the Medicare Shared Savings Program under which providers of services and suppliers, known as

Accountable Care Organizations, can continue to receive traditional fee-for-service payments under Parts A and B of Medicare and also be eligible for additional payments if they meet specified quality and savings requirements.

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 SHARED SAVINGS PROGRAM:
ACCOUNTABLE CARE ORGANIZATIONS"
(RIN: 0938-AQ22)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. According to CMS, the estimated start-up costs for participating Accountable Care Organizations (ACOs) range from \$29 million to \$157 million, with annual ongoing costs ranging from \$63 million to \$342 million, for the anticipated range of 50 to 270 participating ACOs. If ACOs participate at the mean rate, the estimated aggregate average start-up investment and 4-year operating cost is \$451 million. The benefits identified by CMS are improved health care delivery and quality of care and better communication to beneficiaries through patient-centered care.

(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 and therefore performed a Regulatory Flexibility Analysis. CMS found that the total median bonus payments will exceed the average costs borne by participants in the program.

(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 include any mandate that would result in spending by any state, local, or tribal government, in the aggregate, or by the private sector of \$100 million (\$136 million adjusted for inflation) in any one year. CMS acknowledged that there will be costs borne by the private sector in order to participate in the program, but that participation is voluntary and not mandatory.

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

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

On April 7, 2011, CMS published a proposed rule. 76 Fed. Reg. 19,528. CMS received approximately 1,320 public comments on the proposed rule, to which it responded in this final rule.

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

The requirements of the Act do not apply to this program. 42 U.S.C. § 1899(e).

Statutory authorization for the rule

CMS promulgated this rule under the authority of sections 1102, 1106, 1871, and 1899 of the Social Security Act. 42 U.S.C. §§ 1302, 1306, 1395hh, and 1395jjj.

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

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

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not explicitly or implicitly preempt any state law and that the rule will not have a substantial direct effect on state or local governments or otherwise have federalism implications.