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June 23, 2015

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 Paul Ryan
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" (ACOs) (RIN: 0938-AS06). We received the rule on June 4, 2015. It was published in the *Federal Register* as a final rule on June 9, 2015. 80 Fed. Reg. 32,692.

The final rule addresses changes to the Medicare Shared Savings Program, including provisions relating to the payment of ACOs participating in the Medicare Shared Savings Program. Under the Medicare Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee-for-service payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets 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
Deputy Director, Office of Documents and
Regulations Management
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-AS06)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS estimated that the total aggregate median impact would increase to \$780 million in net federal savings for calendar years (CYs) 2016 through 2018. Such median estimated federal savings are \$240 million greater than the \$540 million median net savings estimated at baseline absent the changes adopted in this final rule. CMS found that a key driver of the anticipated increase in net savings is improved Accountable Care Organization (ACO) participation levels in a second agreement period. CMS estimates that at least 90 percent of eligible ACOs will renew their participation in the Shared Savings Program when presented with the new options, primarily under Track 1 and, to a lesser extent, under Track 3. This expansion in the number of ACOs willing to continue their participation in the program is estimated to result in additional improvements in care efficiency of a magnitude significantly greater than the reduced shared loss receipts estimated at baseline and the added shared savings payments flowing from a higher sharing rate in Track 3 and continued one-sided sharing available in Track 1, with all three tracks operating under generally more favorable rebasing parameters including equal base year weighting and adding a portion of savings from the prior agreement period to the baseline.

In addition, at the anticipated mean participation rate of ACOs in the Shared Savings Program, participating ACOs may experience an estimated aggregate average start-up investment and ongoing operating cost of \$822 million for CYs 2016 through 2018. Lastly, CMS estimates an aggregate median impact of \$1,130 million in shared savings payments to participating ACOs in the Shared Savings Program for CYs 2016 through 2018. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield shared savings payments to ACOs of \$960 million and \$1,310 million, respectively. Therefore, the total median ACO shared savings payments of \$1,130 million during CYs 2016 through 2018, net of a median \$30 million shared losses, coupled with the aggregate average start-up investment and ongoing operating cost of \$822 million yields a net private benefit of \$278 million.

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

CMS prepared a Regulatory Impact Analysis (RIA) for this final rule which included a statement of need, anticipated effects, and alternatives considered. CMS determined that this final rule will have a significant impact on a substantial number of small entities and discussed these impacts, including costs and benefits to small entities and alternative policy considerations, throughout the RIA. However, total median shared savings payments net of shared losses will offset about 134 percent of the average costs borne by entities participating in the Shared

Savings Program, with an offset significantly greater than the cost of participation for the subset of ACOs that achieve shared savings in a given year, and no downside risk of significant shared losses for ACOs choosing to remain under Track 1 for a second agreement period.

(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 state, local, or tribal governments, in the aggregate, or by the private sector in the amount of \$100 million (\$144 million, adjusted for inflation) in any 1 year. Further, participation in this program is voluntary and is not mandated.

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

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

On December 8, 2014, CMS published a proposed rule. 79 Fed. Reg. 72,760. CMS received 275 timely comments on the proposed rule. Summaries of the public comments that were within the scope of this rule and CMS's responses to those comments are set forth in the rule.

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

The Act does not apply to the Shared Savings Program. 42 U.S.C. § 1395jjj(e).

Statutory authorization for the rule

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

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

CMS determined that this final rule is economically significant as measured by the \$100 million threshold. CMS submitted the rule to the Office of Management and Budget for review.