



441 G St. N.W.  
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January 15, 2019

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

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

The Honorable Richard Neal  
Chairman  
The Honorable Kevin Brady  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017*

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 and Medicaid Services (CMS) entitled “Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017” (RINs: 0938-AT45; 0938-AT51). The rule was received by the House of Representatives and the Senate on December 27, 2018. We received the rule on December 28, 2018. It was published in the *Federal Register* as a final rule on December 31, 2018. 83 Fed. Reg. 67,816. The effective date of the final rule is February 14, 2019.

The final rule provides a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage Accountable Care Organizations (ACOs) to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses). CMS stated that these policies are designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. This

final rule also provides new tools to support coordination of care across settings and strengthen beneficiary engagement and ensure rigorous benchmarking.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This rule was received by Congress on December 27, 2018. It was published in the *Federal Register* on December 31, 2018, and has a stated effective date of February 14, 2019. Therefore, the final rule does not have a 60-day delay in its effective date.

However, the 60-day delay in effective date can be waived if the agencies find for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agencies incorporate a statement of the findings and their reasons in the rule issued. 5 U.S.C. § 808(2). CMS found good cause for an exception to the effective date to be 45 days from the date of publication in the *Federal Register*. According to CMS, allowing for the final policies to become effective 60 days after the publication of this final rule would provide ACOs with less time to submit their applications and correct deficiencies, contract their provider networks, and establish repayment mechanisms. Therefore, CMS found that it would be impracticable and unnecessary to delay the effective date of this rule.

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. 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

Julia C. Matta  
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas  
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 AND MEDICAID SERVICES  
ENTITLED  
“MEDICARE PROGRAM; MEDICARE SHARED SAVINGS PROGRAM;  
ACCOUNTABLE CARE ORGANIZATIONS—PATHWAYS TO SUCCESS  
AND EXTREME AND UNCONTROLLABLE CIRCUMSTANCES POLICIES  
FOR PERFORMANCE YEAR 2017”  
(RINs: 0938-AT45; 0938-AT51)

(i) Cost-benefit analysis

Using the wage information from the Bureau of Labor Statistics for medical and health service managers (Code 11–9111), the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) estimated that the cost of reviewing this rule is \$107.38 per hour, where the assumed hourly wage of \$53.69 has been increased by a factor of 2 to account for fringe benefits. Assuming an average reading speed of 250 words per minute, CMS estimated it will take approximately 9 hours for staff to review half of this final rule. For each Accountable Care Organizations (ACO) the estimated cost is \$966 (9 hours × \$107.38 per hour). Therefore, CMS estimated the total cost of reviewing this final regulation is approximately \$542,000. CMS also estimated a total net added burden of approximately \$3.3 million over 10 years for the modified beneficiary notification requirements in the final rule.

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

CMS acknowledged that although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a fee-for-service basis, the program can affect many small entities. CMS stated that it developed the rules and regulations accordingly in order to minimize costs and administrative burden on such entities.

(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 will result in spending by state, local, or tribal governments, in the aggregate, or by the private sector in the amount of \$150 million 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.*

On August 17, 2018, CMS issued a proposed rule. 83 Fed. Reg. 41,786. CMS responded to comments in the final rule.

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

CMS stated that section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, according to CMS, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

Statutory authorization for the rule

CMS stated that this rule was promulgated pursuant to 42 U.S.C. §§ 1302, 1306, 1395hh, and 1395jjj.

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

CMS determined that this rule is economically significant as measured by the \$100 million threshold. According to CMS, it prepared a regulatory impact analysis that presents the costs and benefits of the rulemaking.

Executive Order No. 13,132 (Federalism)

CMS stated that it examined the impacts of this final rule as required by the Order.