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November 21, 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: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models*

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; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models" (RIN: 0938-AS69). We received the rule on October 20, 2016. It was published in the *Federal Register* as a final rule with comment period on November 4, 2016, with an effective date of January 1, 2017. 81 Fed. Reg. 77,008.

The final rule repeals the Medicare sustainable growth rate (SGR) methodology for updates to the physician fee schedule (PFS) and replaces it with a new approach to payment called the Quality Payment Program that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and the Merit-based Incentive Payment System (MIPS) for eligible clinicians or groups under PFS. The final rule establishes incentives for participation in certain alternative payment models (APMs) and includes the criteria for use by the Physician Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations on physician-focused payment

models (PFPs). The final rule also establishes the MIPS, a new program for certain Medicare-enrolled practitioners.

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: Vanessa Jones
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
"MEDICARE PROGRAM; MERIT-BASED INCENTIVE PAYMENT
SYSTEM (MIPS) AND ALTERNATIVE PAYMENT MODEL (APM)
INCENTIVE UNDER THE PHYSICIAN FEE SCHEDULE, AND
CRITERIA FOR PHYSICIAN-FOCUSED PAYMENT MODELS"
(RIN: 0938-AS69)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services (CMS) summarized the costs and benefits of this final rule. CMS found that the costs for implementation and complying with the advancing care information performance category requirements could potentially lead to higher operational expenses for Merit-based Incentive Payment System (MIPS) eligible clinicians. Additionally, according to CMS, the costs for implementation and complying with the improvement activities performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices. Health information technology vendors may face additional costs in the transition year of MIPS if they choose to develop additional capabilities in their systems in order to submit advancing care information and improvement activities performance category data on behalf of MIPS eligible clinicians. CMS used a table in the final rule to outline the estimated federal costs.

CMS found the benefits of the final rule include improving quality and value of care provided to Medicare beneficiaries. Additionally, CMS expects that over time clinician engagement in the Quality Payment Program will increasingly result in improved quality of care, resulting in lower morbidity and mortality, and in reduced spending, as physicians respond to the incentives offered by the MIPS and Alternative Payment Models (APMs) and adjust their clinical practice in order to maximize their performance on specified quality measures and activities.

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

CMS found that because there are so many affected MIPS eligible clinicians, even if a small proportion is significantly adversely affected, the number could be substantial. Therefore, CMS was unable to conclude that an Initial Regulatory Flexibility Analysis is not required. CMS stated that the analysis and discussion provided in section IV of the final rule and the analysis found elsewhere in the final rule meet the requirements for an Initial Regulatory Flexibility Analysis.

CMS also found that this final rule would 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 found that this final rule would impose no mandates on state, local, or tribal governments or on the private sector because participation in Medicare is voluntary and because physicians and other clinicians have multiple options as to how they will participate under MIPS and discretion over their performance. Additionally, CMS did not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards.

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

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

On May 9, 2016, CMS published a proposed rule. 81 Fed. Reg. 28,162. CMS received 3,875 comments. CMS responded to comments in the final rule.

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

In the proposed rule, CMS solicited public comment on the need for the information collection and its usefulness in carrying out the proper functions of CMS; the accuracy of CMS's estimate of the information collection burden; the quality, utility, and clarity of the information to be collected; and recommendations to minimize the information collection burden on the affected public, including automated collection techniques. 81 Fed. Reg. 28,362. CMS responded to comments in the final rule. CMS's finalized burden estimates are 10,947,453 burden hours and a burden cost of \$1,311,245,806.

Statutory authorization for the rule

CMS stated the rule was promulgated under 42 U.S.C. §§ 1302, 1395hh, and 1395rr(b)(1).

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

CMS determined that this rule is economically significant. Therefore, CMS prepared a regulatory impact analysis that presents the costs and benefits of the rule.

Executive Order No. 13,132 (Federalism)

CMS determined that this rule does not impose any costs on state and local governments.