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December 11, 2017

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

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

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year*

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; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year” (RIN: 0938-AT13). It was published in the *Federal Register* as a final rule with comment period and interim final rule with comment period on November 16, 2017. 82 Fed. Reg. 53,568.

This final rule with comment period provides updates for the second and future years of the Quality Payment Program. Under the Quality Payment Program, which CMS began implementing in calendar year (CY) 2017, eligible clinicians can participate via one of two tracks: Advanced Alternative Payment Models (AAPM) or the Merit-based Incentive Payment System (MIPS). In addition, this rule includes an interim final rule with comment period that addresses extreme and uncontrollable circumstances MIPS eligible clinicians may face as a result of widespread catastrophic events affecting a region or locale in CY 2017, such as Hurricanes Irma, Harvey, and Maria.

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 final rule was received by both the House of Representatives and the Senate on November 3, 2017, but published in the *Federal Register* on November 16, 2017. 163 Cong. Rec. H8521; 163 Cong. Rec. S7060; 82 Fed. Reg. 53,568. It has a stated effective date of January 1, 2018. Therefore, the final rule does not have the required 60-day delay in its effective date. Although CRA was not specifically addressed, we do note that CMS did, however, find good cause to waive notice and comment requirements for the interim final 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. With the exception of the 60-day delay, 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; CY 2018 UPDATES TO THE
QUALITY PAYMENT PROGRAM; AND QUALITY PAYMENT PROGRAM:
EXTREME AND UNCONTROLLABLE CIRCUMSTANCE POLICY
FOR THE TRANSITION YEAR”
(RIN: 0938-AT13)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) discussed the costs and benefits of this final rule with comment period and interim final rule with comment period, including transfers. CMS estimated the rule will result in an increase of between \$1,293 and \$1,518 million in payments for higher performance under the Merit-based Incentive Payment System (MIPS) and to Qualifying Alternative Payment Model Participants from the federal government. CMS also estimated a decrease of \$118 million in transfers for lower performance under MIPS. CMS estimated the regulatory review costs will be \$2.2 million for the final rule with comment period. CMS further estimated that this final rule with comment period will result in approximately \$695 million in collection of information-related burden. However, CMS estimated that the incremental collection of information-related burden associated with this final rule with comment period is an approximately \$13.9 million reduction relative to the baseline burden of continuing the policies and information collections set forth in the CY 2017 Quality Program final rule into CY 2018.

With regard to benefits, CMS expects that the Quality Payment Program will result in quality improvements and improvements to patients' experiences of care as MIPS eligible clinicians respond to the incentives for high-quality care provided by the program and implement care quality improvements in their clinical practices. While CMS did not quantify these effects specifically at this time because it could not project eligible clinicians' behavioral responses to the incentives offered under the Quality Payment Program, CMS believes that changes to clinical care will result in care quality improvements for Medicare beneficiaries and other patients treated by eligible clinicians.

Finally, CMS estimated the extreme and uncontrollable circumstance policy in this interim final rule with comment period could reduce the amount redistributed in the 2019 MIPS payment year by approximately \$19.9 million.

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

CMS determined that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities either by nonprofit status or by having annual revenues that qualify for small business status. CMS determined approximately 622,000 MIPS eligible clinicians will be required to submit data under MIPS. CMS was unable to conclude that this rule will not have a significant impact on a substantial number of small entities. The rule

included a discussion of (1) the impact on other health care programs and providers, (2) alternatives considered, and (3) assumptions and limitations. In addition, CMS certified that this rule will not have a significant impact on the operations of a substantial number of small hospitals located in rural areas.

(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 with comment period imposes 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. Moreover, CMS interprets the act as applying only to unfunded mandates. CMS does 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. CMS applies the interpretation whether the facilities or providers are private, state, local, or tribal.

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

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

On June 30, 2017, CMS published a proposed rule for the CY 2018 Updates to the Quality Payment Program. 82 Fed. Reg. 30,010. CMS received comments on the proposed rule, which CMS summarized and responded to in the final rule as it determined was appropriate. Because of the volume of comments and feedback, CMS stated that it was not able to address all of the comments and issues that were raised.

This rule also includes an interim final rule establishing an extreme and uncontrollable circumstance policy. CMS found good cause to waive notice and comment requirements due to the impact of Hurricanes Harvey, Irma, and Maria. CMS believes it is in the public interest to adopt these interim final policies to provide relief to impacted clinicians to assist them while they direct their resources toward caring for their patients and repairing structural damages to facilities. CMS found that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing, on an interim basis, this policy. CMS provided a comment period for both the final and interim final portions of this rule.

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

CMS determined that this final rule with comment period and interim final rule with comment period contains 18 information collection requirements under the Act. CMS estimated the final rule with comment period will decrease the burden by 171,264 hours and \$13.9 million in labor costs relative to the estimated baseline of continued transition year policies. CMS determined the interim final rule with comment period contained no information collection requirements under the Act.

Statutory authorization for the rule

CMS promulgated this final rule with comment period and interim final rule with comment period under the authority of sections 1102, 1871, and 1881(b)(1) of the Social Security Act. 42 U.S.C. §§ 1302, 1395hh, 1395rr(b)(1).

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

CMS estimated that this final rule with comment period and interim final rule with comment period is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

CMS does not believe any of the policies of this final rule with comment period and interim final rule with comment period impose a substantial direct effect on the Medicaid program as participation in the Payer Initiated Determination Process is voluntary and use of the Eligible Clinician Initiated Determination Process is also voluntary. CMS also stated that it is unaware of any relevant federal rules that duplicate, overlap, or conflict with the final rule with comment period.