



441 G St. N.W.  
Washington, DC 20548

B-330539

December 10, 2018

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 and Medicaid Services: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*

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; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act” (RINs: 0938-AT31; 0938-AT13; 0938-AT45). We received the rule on November 7, 2018. It was published in the *Federal Register* as final rules and an interim final

rule on November 23, 2018. 83 Fed. Reg. 59,452. The effective date of the final rule is January 1, 2019.

The final rule addresses changes to the Medicare physician fee schedule and other Medicare Part B payment policies to ensure that CMS payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the law. This rule also finalizes policies included in the interim final rule with comment period in “Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year” that address the extreme and uncontrollable circumstances Merit-based Incentive Payment System eligible clinicians faced as a result of widespread catastrophic events affecting a region or locale in CY 2017, such as Hurricanes Irma, Harvey, and Maria. In addition, the rule addresses a subset of the changes to the Medicare Shared Savings Program for Accountable Care Organizations proposed in the August 2018 proposed rule “Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success.” The rule also addresses certain other revisions designed to update program policies under the Shared Savings Program.

The interim final rule implements amendments made by the SUPPORT for Patients and Communities Act to the Medicare telehealth provisions in the Social Security Act and regarding permissible telehealth originating sites for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for telehealth services on or after July 1, 2019, to an individual with a substance use disorder diagnosis.

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 published in the *Federal Register* on November 23, 2018. 83 Fed. Reg. 59,452. It was received by the House on November 9, 2018, but the *Congressional Record* does not indicate when it was received by the Senate. It has a stated effective date of January 1, 2019. 1364 Cong. Rec. H9470 (daily ed. Nov. 9, 2018). Therefore, the final rule does not have the required 60-day delay in its effective date.

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: Kathy Applewhite  
Regulations Specialist  
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; REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO PART B FOR CY 2019; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; QUALITY PAYMENT PROGRAM; MEDICAID PROMOTING INTEROPERABILITY PROGRAM; QUALITY PAYMENT PROGRAM—EXTREME AND UNCONTROLLABLE CIRCUMSTANCE POLICY FOR THE 2019 MIPS PAYMENT YEAR; PROVISIONS FROM THE MEDICARE SHARED SAVINGS PROGRAM—ACCOUNTABLE CARE ORGANIZATIONS—PATHWAYS TO SUCCESS; AND EXPANDING THE USE OF TELEHEALTH SERVICES FOR THE TREATMENT OF OPIOID USE DISORDER UNDER THE SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT (SUPPORT) FOR PATIENTS AND COMMUNITIES ACT”  
(RINs: 0938-AT31; 0938-AT13; 0938-AT45)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) stated the rule will benefit patients and physicians by recognizing communication technology-based services. CMS stated these policies will expand access to care and create more opportunities for patients to access more personalized care and create more personalized care management, as well as connect with their physicians more quickly. CMS further stated the policies in the rule will also give physicians more time to spend with their patients rather than on paperwork by simplifying documentation requirements.

However, CMS stated the rule may create some compliance and modernizations costs on physicians including one time training costs on new patient consultation guidelines, updating existing records and billing systems to comply with reporting guidelines, and the acquisition of electronic health records systems if needed.

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

CMS stated approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based on the Small Business Administration standards. CMS further stated because many of the affected entities are small entities, it completed a Regulatory Flexibility Analysis that was incorporated into the final rule. CMS certified the rule would not have a substantial impact on a significant 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 stated the final rule will impose no mandates on state, local, or tribal governments or on the private sector.

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

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

CMS published a Notice of Proposed Rulemaking on July 27, 2018. 83 Fed. Reg. 35,704. CMS received many comments to which it responded in the rule.

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

CMS stated that it solicited comments to changes in the proposed Collections of Information in the Notice of Proposed Rulemaking and submitted the proposals to the Office of Management and Budget for approval. CMS stated the changes to the Collections of Information would reduce the hourly burden on respondents by 932,880 hours and reduce the financial burdens on respondents by \$146,488,260.

Statutory authorization for the rule

CMS stated it promulgated the rule under 42 U.S.C. §§ 263a, 405(a), 1302, 1302b-12, 1306, 1395w-101 through 1395w-152, 1395x, 1395y(a), 1395ff, 1395hh, 1395nn, 1395kk, 1395rr, 1395ww(k), and 1395jjj.

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

CMS stated the rule had been reviewed by the Office of Management and Budget and a Regulatory Impact Analysis was incorporated in the rule.

Executive Order No. 13,132 (Federalism)

CMS stated the rule does not impose any costs on state or local governments, so the Order does not apply.