U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

B-331620

November 26, 2019

The Honorable Chuck Grassley
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 & Medicaid Services: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule*

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 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory

Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule" (RIN: 0938-AT72). We received the rule on November 5, 2019. It was published in the *Federal Register* as a final rule and interim final rule on November 15, 2019. 84 Fed. Reg. 62568. The stated effective date of the rule is January 1, 2020.

The final rule addresses: (1) changes to the physician fee schedule; (2) other changes to Medicare Part B payment policies to ensure, according to CMS, that payment systems are updated to reflect changes in medical practice, relative value of services and changes in the statute; (3) Medicaid Promoting Interoperability Program requirements for eligible professionals; (4) the establishment of an ambulance data collection system; (5) updates to the Quality Payment Program; (6) Medicare enrollment of opioid treatment programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and (7) amendments to Physician Self-Referral Law advisory opinion regulations. In addition, the interim final rule establishes coding and payment for evaluation and management, observation and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible.

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). The *Congressional Record* indicates both Houses of Congress received the rule on November 5, 2019. 165 Cong. Rec. S6446 (daily ed. Nov. 6, 2019); 165 Cong. Rec. H8782 (daily ed. Nov. 12, 2019). The rule was published in the *Federal Register* on November 15, 2019. 84 Fed. Reg. 62568. The final rule has a stated effective date of January 1, 2020. Therefore, the final rule does not have the required 60-day delay in its effective date. However, the 60-day delay in effective date can be waived if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. §§ 553(b)(3)(B), 808(2). CMS waived notice-and-comment rulemaking procedures for the interim final rule for good cause. CMS found good cause due to the urgent need of some Medicare beneficiaries for effective treatment for treatment-resistant depression, a serious and life-threatening condition. CMS did not waive good cause for the portions of the rule that were not published as an 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. 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT HEALTH AND NUMBER SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; CY 2020 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER CHANGES TO PART B PAYMENT POLICIES; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; MEDICAID PROMOTING INTEROPERABILITY PROGRAM REQUIREMENTS FOR ELIGIBLE PROFESSIONALS; ESTABLISHMENT OF AN AMBULANCE DATA COLLECTION SYSTEM; UPDATES TO THE QUALITY PAYMENT PROGRAM; MEDICARE ENROLLMENT OF OPIOID TREATMENT PROGRAMS AND ENHANCEMENTS TO PROVIDER ENROLLMENT REGULATIONS CONCERNING IMPROPER PRESCRIBING AND PATIENT HARM; AND AMENDMENTS TO PHYSICIAN SELF-REFERRAL LAW ADVISORY OPINION REGULATIONS FINAL RULE; AND CODING AND PAYMENT FOR EVALUATION AND MANAGEMENT, OBSERVATION AND PROVISION OF SELF-ADMINISTERED ESKETAMINE INTERIM FINAL RULE"
(RIN: 0938-AT72)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would lead to a $300 million increase in expenditures from the federal government to physicians, other practitioners and providers, and suppliers who receive payment under Medicare due to an increase in Physician Fee Schedule conversion factor payments. Also, CMS estimated a cost of $100 million for annualized monetized transfers of beneficiary cost coinsurance from beneficiaries to the federal government.

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

CMS stated many of the entities affected by the final rule are small entities and further stated the Regulatory Impact Analysis (RIA) is also intended to satisfy the Regulatory Flexibility Analysis required by the Act. The RIA addresses: (1) the statement of need; (2) overall impact of the final rule; (3) changes in Relative Value Unit impacts; (4) effect of changes related to telehealth; (5) effect of changes related to physician supervision for physician assistant services; (6) other provisions of the regulation; (7) alternatives considered; (8) impact on beneficiaries; (9) burden reduction estimates; and (10) estimations of regulatory familiarization costs. CMS certified the final rule will not have significant impact on 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 determined 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 for the final rule on August 14, 2019. 84 Fed. Reg. 40482. CMS responded to comments in the final rule. As for the interim final rule, CMS waived notice-and-comment rulemaking procedures for good cause. CMS found good cause due to the urgent need of some Medicare beneficiaries for effective treatment for treatment-resistant depression, a serious and life-threatening condition. CMS opened a comment period for the interim final rule; the comment period closes December 31, 2019.

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act. CMS submitted the ICRs to the Office of Management and Budget (OMB) for review. The ICRs are associated with OMB Control Numbers 0938-0921; 0938-0776; 0938-1237; 0938-0685; 1110-0046; 0938-0832; 0938-1314; 0938-1222; 0938-1343; and 0938-1197. CMS estimated the changes to the ICRs would lead to a reduction of 1,722,544 burden hours and a reduction in costs of $166,778,034.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1320a-7j, 1395i-3, 1395w-101 *et seq*., 1395x, 1395aa, 1395cc, 1395ff, 1395hh, 1395nn, 1395rr, and 1395jjj of title 42, United States Code.

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

CMS determined the final rule was economically significant and submitted the rule to OMB for review.

Executive Order No. 13,132 (Federalism)

CMS determined the final rule does not impose any costs on state or local governments.