U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-332097

April 22, 2020

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 and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency*

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 and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency" (RIN: 0938-AU31). We received the rule on April 9, 2020. It was published in the *Federal Register* as an interim final rule with comment period on April 6, 2020. 85 Fed. Reg. 19230. The effective date of the rule is March 31, 2020. The applicability date of the final rule is March 1, 2020.

According to CMS, the interim final rule gives individuals and entities that provide services to Medicare beneficiaries the flexibilities to respond to the public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19). CMS stated it is changing Medicare payment rules during the Public Health Emergency (PHE) for the COVID-19 pandemic so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics, and federally qualified health centers are allowed broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community. According to CMS, the interim final rule also alters the applicable payment policies to provide specimen collection fees for independent laboratories

collecting specimens from beneficiaries who are homebound or inpatients (not in a hospital) for COVID-19 testing. CMS stated it is also expanding, on an interim basis, the list of destinations for which Medicare covers ambulance transports under Medicare Part B. According to CMS, the interim final rule makes programmatic changes to the Medicare Diabetes Prevention Program and the Comprehensive Care for Joint Replacement Model in light of PHE, and program-specific requirements for the Quality Payment Program to avoid inadvertently creating incentives to place cost considerations above patient safety. CMS stated the interim final rule modifies the calculation of the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection and measure scores posed by the COVID-19 pandemic and also, according to the agency, to avoid inadvertently creating incentives to place cost considerations above patient safety. CMS stated the interim final rule also amends the Medicaid home health regulations to allow other licensed practitioners to order home health services, for the period of this PHE for the COVID-19 pandemic in accordance with state scope of practice laws. CMS also stated the final rule modifies CMS's under arrangements policy during the PHE for the COVID-19 pandemic so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital.

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 60-day delay in effective date can be waived, however, 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). Here, although CMS did not specifically mention CRA's 60-day delay in effective date requirement, the agency found good cause to waive notice and comment procedures and incorporated a brief statement of the reasons. Specifically, CMS determined it had good cause to wave notice and comment procedures because the nation is experiencing an emergency of unprecedented magnitude due to the COVID-19 pandemic. According to CMS, the interim final rule advances the goal of ensuring the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers during the COVID-19 pandemic by providing flexibilities in providing services and ensuring sufficient health care items and services to meet needs during the pandemic.

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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

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 HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS;
POLICY AND REGULATORY
REVISIONS IN RESPONSE TO THE
COVID–19 PUBLIC HEALTH EMERGENCY"
(RIN: 0938-AU31)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the interim final rule would cost providers $333,049.50 to implement changes in response to COVID-19. In particular, CMS identified costs associated with waiving the once-per-lifetime requirement and the minimum weight loss requirement, among others, as part of the Medicare Diabetes Prevention Program.

CMS estimated the interim final rule would lead to a savings of $153.5 million by permitting advanced practice providers of psychiatric services to treat patients and make progress notes, removing the current requirement that only medical doctors can do this. CMS also estimated accountable care organizations could experience total savings of approximately $20 million due to changes in the extreme and uncontrollable circumstances policy of the Shared Savings Program. CMS stated the interim final rule also provides greater flexibility to beneficiaries by increasing the number of permitted virtual sessions.

Also, CMS stated it anticipates an additional transfer of $0 to $1.2 million in federal payments to providers because the interim final rule extends the Comprehensive Care for Joint Replacement Model for Performance Year 5 by 3 months.

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

CMS stated while most hospitals and other health care providers are small entities, CMS measures a significant economic impact to be an adverse change in revenues of more than 3 to 5 percent. CMS stated it did not think the interim final rule would reach that threshold. CMS also stated the interim final rule will 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 determined the interim final rule does not impose any mandate, on an unfunded basis, on any state, tribal, or local government 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 waived notice-and-comment rulemaking for good cause. CMS determined it had good cause because the nation is experiencing an emergency of unprecedented magnitude due to the COVID-19 pandemic. According to CMS, the interim final rule advances the goal of ensuring the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers during the COVID-19 pandemic by providing flexibilities in providing services and ensuring sufficient health care items and services to meet needs during the pandemic. With publication of this interim final rule, CMS also opened a comment period that ends on June 1, 2020.

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

CMS determined the interim final rule impacts information collection requirements associated with Office of Management and Budget (OMB) Control Numbers 0938-1028 and 0938-0732. The interim final rule eliminates the requirement to collect and submit data for these control numbers, thus reducing the burden. CMS will revise the estimated burden hours to reflect the decrease when it resubmits the control numbers for renewal.

Statutory authorization for the rule

CMS promulgated the interim final rule pursuant to section 9701 of title 3; sections 263a, 300e, 300e-5, 300e-9, 405, 1302, 1306, 1315a, 1320b-12, 1395m, 1395x, 1395y, 1395w-101 through 1395w-152, 1395ff, 1395hh, 1395kk, 1395rr, 1395ww, 1395ddd, 1395jjj, 1395lll of title 42; and sections 3501—3583 of title 44, United States Code.

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

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

Executive Order No. 13,132 (Federalism)

CMS determined the interim final rule does not have a substantial direct cost impact on state or local governments, preempt state law, or otherwise have federalism implications.