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May 26, 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, Office of the Secretary: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program*

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 (HHS), Centers for Medicare & Medicaid Services (CMS), Office of the Secretary entitled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (RIN: 0938-AU32). We received the rule on May 11, 2020. It was published in the *Federal Register* as an interim final rule with comment period on May 8, 2020. 85 Fed. Reg. 27550. The effective date of the rule is May 8, 2020. The applicability date of the rule is March 1, 2020, or January 27, 2020, or as otherwise specified.

According to CMS, this interim final rule revises existing regulations to offer health care providers and suppliers additional flexibilities in furnishing services to combat the COVID-19 pandemic, and implements new regulations in response to recent legislation including the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, the Families

First Coronavirus Response Act, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Pub. L. No. 116-136, 134 Stat. 281 (Mar. 27, 2020); Pub. L. No. 116-127, 134 Stat. 178 (Mar. 18, 2020); Pub. L. No. 116-123, 134 Stat. 146 (Mar. 6, 2020). According to CMS, the rule will ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the programs under title XVIII (Medicare) and title XIX (Medicaid) of the Social Security Act, or in certain programs authorized under the Affordable Care Act. CMS states the rule will increase access to hospital and community mental health services furnished in temporary expansion locations of the hospital including the patient's home, increase access to laboratory and diagnostic testing in a patient's home or other settings that could help minimize transmission of communicable disease, and improve infection control. According to CMS, the rule will also amend Shared Savings Program regulations to encourage continued participation by Accountable Care Organizations during the pandemic. According to CMS, the rule permits a state operating a Basic Health Program (BHP) to seek certification for temporary significant changes to its BHP Blueprint that are directly tied to the Public Health Emergency (PHE) for the COVID-19 pandemic. CMS states the rule also delays by 60 days the date when Qualified Health Plan issuers must be in compliance with the separate billing policy in order to enable issuers to divert resources to respond to the COVID-19 pandemic. Finally, CMS states that, consistent with section 3708 of the CARES Act, the rule permits nurse practitioners, clinical nurse specialists, and physician assistants to certify the need for home health services and to order services in the Medicare and Medicaid programs. See Pub. L. No. 116-136, § 3708.

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. §§ 801(a)(3), 808(2). CMS explained that it would be impracticable and contrary to the public interest not to waive the delay in effective date of the rule under CRA, as that would delay giving providers the flexibilities to provide critical care during the PHE declared for the COVID-19 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 this interim final 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

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,
OFFICE OF THE SECRETARY
ENTITLED
“MEDICARE AND MEDICAID PROGRAMS, BASIC HEALTH PROGRAM,
AND EXCHANGES; ADDITIONAL POLICY AND REGULATORY REVISIONS
IN RESPONSE TO THE COVID-19 PUBLIC HEALTH EMERGENCY
AND DELAY OF CERTAIN REPORTING REQUIREMENTS
FOR THE SKILLED NURSING FACILITY QUALITY REPORTING PROGRAM”
(RIN: 0938-AU32)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this interim final rule. This analysis identified whether CMS anticipated any changes to Medicare expenditures as a result of the rule. To estimate the rule’s impact on Medicare expenditures, CMS considered the rule’s effects on Medicare services and reimbursements, such as: changes in the number of services furnished under the Medicare program; changes in Medicare payment rates; changes to a per-visit national payment limit or graduate medical education payments; changes in the amounts of shared savings payments made to Accountable Care Organizations (ACOs) enrolled in the Shared Savings Program; changes to the number of Medicare beneficiaries.

CMS identified reduced transfers associated with this interim final rule as a result of the reduction in Medicare payments to ACOs, Medicare-enrolled suppliers, providers, and practitioners. CMS estimated that at a discount rate of 7 percent the reduced transfer will be -\$269.6 million for the period of calendar years 2020 through 2025, and at a discount rate of 3 percent the reduced transfer will be -\$250.8 million for the same period.

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

CMS determined that this interim final rule will not have a significant economic impact on a substantial number of small entities. CMS also determined that the 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 that this interim final rule does not mandate, on an unfunded basis, any requirements for state, local, or tribal governments, or for the private sector.

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

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

On May 8, 2020, CMS published this interim final rule. 85 Fed. Reg. 27550. CMS issued the rule without prior notice and opportunity to comment, with an immediate effective date, and with

an applicability date of March 1, 2020, or January 27, 2020, or as otherwise specified. CMS explained that it has found good cause to waive notice and comment rulemaking because it would be impracticable and contrary to the public interest to undertake normal notice and comment rulemaking procedures, as that would delay giving providers the flexibilities to provide critical care during the Public Health Emergency (PHE) declared for the coronavirus disease 2019 (COVID–19) pandemic. For the same reasons, CMS found good cause to waive the 30-day delay in the effective date, and moreover, to make certain policies in the rule applicable as of March 1, 2020—the date the President of the United States declared as the beginning of the national emergency concerning the COVID–19 pandemic, or, if applicable, January 27, 2020, the date on which the PHE for the COVID–19 pandemic began.

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

CMS determined that this interim final rule contains information collection requirements (ICRs) under the Act. CMS created new information collection requests associated with the rule and submitted them to the Office of Management and Budget (OMB) for approval. CMS identified ICRs associated with the temporary extraordinary circumstances policy for relocating excepted provider-based departments during the COVID–19 PHE and submitted them to OMB for approval. For these ICRs, CMS estimated 113 total burden hours and a labor cost of \$6,257. CMS also identified ICRs associated with the policy to allow nurse practitioners, clinical nurse specialists, and physician assistants to certify the need for home health services and submitted them to OMB for approval. For these ICRs, CMS estimated 1,333 total burden hours and a cost of \$131,160. CMS created a new information collection request associated with the requirement for long-term care facilities to electronically report information related to confirmed or suspected COVID–19 cases in a standardized format and frequency and will submit the request to OMB for approval. This ICR is entitled “National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID–19) Surveillance in Healthcare Facilities” (OMB control number 0920–1290). For this request, CMS estimated 349,731 total burden hours and a cost of \$16,402,763. CMS estimates a reduction in burden hours and cost associated with the existing ICR, “Billing and Collection of the Separate Payment for Certain Abortion Services” (OMB control number 0938-1358), which the agency will include in its next submission of the ICR to OMB.

Statutory authorization for the rule

CMS promulgated this temporary final rule pursuant to various sections of title 42, United States Code, section 9701 of title 31, United States Code, section 36B of title 26, United States Code, and section 1331 of the Patient Protection and Affordable Care Act of 2010, as amended, classified at section 18051 of title 42, United States Code.

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

OMB determined that this rule is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

CMS has determined that this final rule does not have a substantial direct cost impact on state or local government, preempt state law, or otherwise have federalism implications.