U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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September 17, 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, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional 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, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency" (RIN: 0938-AU33). We received the rule on August 28, 2020. It was published in the *Federal Register* as an interim final rule with comment period on September 2, 2020. 85 Fed. Reg. 54820. The effective date of the interim final rule is September 2, 2020.

According to CMS, the interim final rule revises regulations to strengthen CMS's ability to enforce compliance with Medicare and Medicaid long-term care (LTC) facility requirements for reporting information related to coronavirus disease 2019 (COVID–19), establishes a new requirement for LTC facilities for COVID–19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID–19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to

report COVID–19 test results to the Secretary of Health and Human Services (Secretary) in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the public health emergency.

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. § 808(2). CMS determined it had good cause because ensuring the health and safety of all Americans, including Medicare beneficiaries, Medicaid recipients, and healthcare workers is of primary importance. CMS stated this interim final rule directly supports that goal by requiring COVID–19 reporting by hospitals, CAHs, and CLIA laboratories; by requiring testing of nursing home staff and residents; and by strengthening enforcement of important nursing home infection prevention and control requirements related to COVID–19 reporting. According to CMS, it is critically important that it implement the policies in this interim final rule as quickly as possible.

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 OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS,
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA), AND
PATIENT PROTECTION AND AFFORDABLE CARE ACT;
ADDITIONAL POLICY AND REGULATORY REVISIONS
IN RESPONSE TO THE COVID–19 PUBLIC HEALTH EMERGENCY"
(RIN: 0938-AU33)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) estimated the interim final rule would lead to increased costs for regulated entities, including daily costs, with a low estimate of $710,316,308 and high estimate of $4,275,937,280. CMS further estimated the interim final rule would create one-time costs to the regulated entities, with a low estimate of $145,243,610 and a high estimate of $176,529,968.

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

CMS determined the interim final rule will have a significant economic impact on a substantial number of small entities. CMS also determined the interim final rule will have a significant economic impact on a substantial number of 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 interim final rule was not subject to the requirements of the Act because it was not preceded by a general notice of proposed rulemaking.

(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 proceedings for good cause. CMS stated it had good cause because ensuring the health and safety of all Americans, including Medicare beneficiaries, Medicaid recipients, and healthcare workers is of primary importance. CMS stated this interim final rule directly supports that goal by requiring coronavirus disease 2019 (COVID–19) reporting by hospitals, critical access hospitals, and Clinical Laboratory Improvement Amendments laboratories; by requiring testing of nursing home staff and residents; and by strengthening enforcement of important nursing home infection prevention and control requirements related to COVID–19 reporting. According to CMS, it is critically important that it implement the policies in this interim final rule as quickly as possible.

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

CMS determined the interim final rule contained information collection requirements (ICRs) subject to the Act. The ICRs include an information collection related to laboratory test reporting (Office of Management and Budget (OMB) Control Number 0920-1299); an information collection associated with the HHS Teletracking COVID–19 Portal form (OMB Control Number 0990-NEW); and an information collection regarding the requirements for long-term care facilities to test residents and staff for COVID–19 (OMB Control Number 0938-NEW). The interim final rule also modified two existing ICRs: "Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals" (OMB Control Number 0938-1155); and "Medical Loss Ratio Reports, MLR Notices, and Recordkeeping Requirements" (OMB Control Number 0938-1164). CMS estimated the total hourly burden for all ICRs in the interim final rule to increase by 1,386,873 hours and the total cost to increase by $173,382,935.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 236a, 1302, 1306, 1320, 1320a-7, 1395d, 1395f, 1395g, 1395i, 1395*l*, 1395m, 1395w-101 *et seq.*, 1395x, 1395hh, 1395rr, 1395tt, 1395ww, 1395ddd, and 1396r of title 42, United States Code.

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

CMS determined the interim final rule is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

CMS determined the interim final rule would have a substantial direct effect on state or local governments. CMS stated the interim final rule would also have a direct effect on preempting state laboratory requirements as they must change their current laboratory standards to remain equal to or more stringent than federal laws when finalized.