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Washington, DC 20548

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December 2, 2020

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary: Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes 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, Office of the Secretary (HHS) entitled "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency" (RIN: 0955-AA02). We received the rule on November 23, 2020. It was published in the *Federal Register* as an interim final rule with comment period on November 4, 2020. 85 Fed. Reg. 70064. HHS opened a comment period closing on January 4, 2021. The effective date of the rule is December 4, 2020.

According to HHS, the interim final rule gives health IT developers and health care providers flexibilities to effectively respond to the public health threats posed by the spread of the coronavirus disease 2019 (COVID-19). Recognizing the urgency of this situation, and understanding that caring for patients with COVID-19 is of utmost importance, HHS stated it is issuing the interim final rule to extend certain compliance dates and timeframes adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including compliance and applicability dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification requirements under the ONC Health IT Certification Program (Program). HHS also stated the interim final rule makes programmatic changes to the Program by updating standards. HHS further stated the interim final rule also makes corrections and clarifications to the ONC Cures Act Final Rule.

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 HHS did not specifically mention CRA's 60-day in effective date requirement, the agency found good cause to waive notice and comment procedures under the Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(B), and incorporated a brief statement of reasons. Specifically, HHS determined it had good cause because the nation is experiencing an emergency of unprecedented magnitude. HHS stated the interim final rule offers regulated individuals and entities flexibilities in complying with the ONC Cures Act Final Rule while they are combating the COVID-19 pandemic. HHS further stated the interim final rule also helps to ensure that sufficient health IT products and services are available to meet the needs of affected health care systems, health care providers, and individuals.

Enclosed is our assessment of HHS'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.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large, prominent initial 'S'.

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 OF HEALTH AND HUMAN SERVICES,
OFFICE OF THE SECRETARY
ENTITLED
“INFORMATION BLOCKING AND THE ONC HEALTH IT
CERTIFICATION PROGRAM: EXTENSION OF COMPLIANCE DATES
AND TIMEFRAMES IN RESPONSE TO THE
COVID-19 PUBLIC HEALTH EMERGENCY”
(RIN: 0955-AA02)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) stated it was unable to identify any new quantifiable costs or benefits as a result of the provisions in this interim final rule. HHS stated this is because the provisions in the interim final rule are limited in nature: applicability and compliance date extensions, standards updates, and regulatory clarifications and corrections.

HHS also stated there are unquantifiable costs and benefits of the interim final rule, as the extensions in the interim final rule respond to developers' need for additional time to meet the deadlines due, in part, to external factors, such as the coronavirus disease 2019 (COVID-19).

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

HHS certified the interim final rule will not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

HHS determined the interim final rule is not expected to result in expenditures by state, local, and tribal governments, or by the private sector, of \$156 million (\$100 million, adjusted for inflation) or more in any one year.

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

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

HHS waived notice and comment procedures and the 30-day delayed effective date for good cause. HHS determined it had good cause because the nation is experiencing an emergency of unprecedented magnitude. HHS stated the interim final rule offers regulated individuals and entities flexibilities in complying with the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule) while they are combating the COVID-19 pandemic. HHS further stated the interim final rule also helps to ensure that sufficient health IT products and services are available to meet the needs of affected health care systems, health care providers, and individuals. According to HHS, it cannot afford a delay in effectuating this interim final rule and does not want to create

unnecessary burdens on stakeholders who would otherwise adhere to the compliance and applicability dates in the ONC Cures Act Final Rule.

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

HHS determined the interim final rule does not contain any information collection requirements subject to the Act.

Statutory authorization for the rule

HHS promulgated the final rule pursuant to sections 300jj-11, 300jj-14, and 300jj-52 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS determined the interim final rule is economically significant pursuant to the Order.

Executive Order No. 13132 (Federalism)

HHS determined the interim final rule does not impose any costs on state or local governments, and the Order was not applicable.