U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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December 8, 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

Subject: *Department of Health and Human Services, Office of the Secretary: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification 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), Office of the Secretary entitled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (RIN: 0955-AA01). We received the rule on November 23, 2020. It was published in the *Federal Register* as a final rule on May 1, 2020. 85 Fed. Reg. 25642. The stated effective date of the rule is June 30, 2020.

HHS states this final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. 42 U.S.C. § 201 note. According to HHS, the implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. HHS states the rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

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 final rule was published in the *Federal Register* as a final rule on May 1, 2020. 85 Fed. Reg. 25642. The *Congressional Record* reflects that the House received the final rule on November 24, 2020. 166 Cong. Rec. H6857 (daily ed. Dec. 4, 2020). The *Congressional Record* does not reflect the date of receipt by the Senate.

The stated effective date of the final rule is June 30, 2020. Therefore, the final rule does not have the required 60-day delay in its effective date.

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.

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,
OFFICE OF THE SECRETARY
ENTITLED
"21ST CENTURY CURES ACT: INTEROPERABILITY,
INFORMATION BLOCKING, AND THE
ONC HEALTH IT CERTIFICATION PROGRAM"
(RIN: 0955-AA01)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC) conducted a cost-benefit analysis of this final rule. In its analysis, HHS estimated the monetary costs and benefits of this final rule for health IT developers, health care providers, patients, ONC-Authorized Certification Bodies (ONC-ACBs), ONC-Authorized Testing Laboratories (ONC-ATLs), and the federal government, and has broken those costs and benefits out into categories of (1) deregulatory actions (no associated costs); (2) updates to the 2015 Edition health IT certification criteria; (3) Conditions and Maintenance of Certification requirements for a health IT developer; (4) oversight for the Conditions and Maintenance of Certification requirements; and (5) information blocking.

HHS expects the rule to have a quantified cost of $852 million, annualized over 10 years at a discount rate of 3 percent, and a quantified cost of $396 million, annualized over 10 years at a discount rate of 7 percent. According to HHS, the rule will have non-quantifiable costs, including the impact of provisions on health IT production costs such as the supply and demand for personnel over time; costs for developers to correct non-conformities; ONC cost to review non-conformities, real-world testing maintenance by ONC-ACBs; additional provider implementation activities related to adoption of the United States core data for interoperability (USCDI) as a standard and data segmentation for privacy certification (DS4P) criteria; and the cost of external regulatory and policy activities.

HHS also expects the rule to have a quantified benefit of $3,089 million, annualized over 10 years at a discount rate of 3 percent, and a quantified benefit of $2,184 million, annualized over 10 years at a discount rate of 7 percent. HHS states the rule will have non-quantifiable benefits from its impact on users of health IT that were ineligible or did not participate in the Centers for Medicare & Medicaid Services' Electronic Health Record Incentive Programs; developer cost savings from no longer supporting the 2014 Edition; provider and patient benefit from implementation of USCDI and DS4P provisions due to improvements in interoperability; benefits associated with the communication provision; the benefit of ONC oversight on real world testing and non-conformance; and the benefit of external regulatory and policy activities.

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

HHS certifies that this final rule will not have a significant 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 stated that it does not believe this final rule imposes unfunded mandates on state, local, and tribal governments or 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 March 4, 2019, HHS published a proposed rule. 84 Fed. Reg. 7424. HHS received comments on the proposed rule and responded to the comments in the final rule.

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

HHS determined that this final rule contains information collection requirements under the Act. For the requirement under section 170.523(p)(3) of the rule for ONC-ACBs to collect and report certain information to ONC related to real world testing plans and results, HHS estimates fewer than 10 annual respondents and therefore determined this requirement was not subject to the Act, citing 5 C.F.R. § 1320.3(c). HHS also stated that of the two separate collections from health IT developers in the rule, the process requiring health IT developers to submit information to ONC to facilitate and conclude ONC's review of their compliance with Conditions and Maintenance Certification requirements is exempt from the Act under 44 U.S.C. § 3518(c)(1)(B)(ii), as a collection activity during the conduct of administrative actions or investigations involving the agency against specific individuals or entities. For the other collection from health IT developers requiring them to retain, for a period of 10 years, all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the Program for each health IT product, HHS estimated the annualized total burden to be 47,632 hours.

Statutory authorization for the rule

HHS promulgated this final rule pursuant to sections 300jj-11, 300jj-14, and 300jj-52 of title 42, and sections 552 and 553 of title 5, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

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

Executive Order No. 13132 (Federalism)

HHS stated that this final rule does not impose substantial direct compliance costs on state and local governments, preempt state law, or otherwise have federalism implications.