



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

B-335877

January 25, 2024

The Honorable Bernard Sanders  
Chairman  
The Honorable Bill Cassidy  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Cathy McMorris Rodgers  
Chair  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*

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 “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (RIN: 0955-AA03). We received the rule on January 10, 2024. It was published in the *Federal Register* as a final rule on January 9, 2024. 89 Fed. Reg. 1192. The stated effective date is February 8, 2024.

HHS states that the final rule implements the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act, Pub. L. 114-255, 130 Stat. 1033, (Dec. 13, 2016), by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program (Program). HHS further states that the final rule makes several updates to certification criteria and standards recognized by the Program. According to HHS, these Program updates include revised certification criteria for “decision support interventions,” “patient demographics and observations,” and “electronic case reporting,” as well as a new baseline version of the United States Core Data for Interoperability (USCDI) standard to Version 3. Additionally, HHS states that the final rule provides enhancements to support information sharing under information blocking regulations. HHS states that the implementation of these provisions advances interoperability, improves algorithm transparency, and supports the access, exchange, and use of electronic health information (EHI). Finally, HHS states that the final rule updates numerous technical standards in the Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.

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 *Congressional Record* reflects receipt by both the House and Senate on January 10, 2024. See 170 Cong. Rec. H105 (Jan. 11, 2024); 170 Cong. Rec. S146 (Jan. 17, 2024). The rule was published in the *Federal Register* on January 9, 2024, and it has a stated effective date of February 8, 2024. 89 Fed. Reg. 1192. 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.

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

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  
“HEALTH DATA, TECHNOLOGY, AND INTEROPERABILITY:  
CERTIFICATION PROGRAM UPDATES, ALGORITHM TRANSPARENCY,  
AND INFORMATION SHARING”  
(RIN: 0955-AA03)

(i) Cost-benefit analysis

The Department of Health and Human Services, Office of the Secretary, (HHS) conducted a cost-benefit analysis with respect to the final rule. HHS estimated that the total annual cost for the final rule for the first year after it is finalized (including one-time costs), based on the cost estimates outlined throughout HHS’s Regulatory Impact Analysis (RIA), would result in \$437 million. HHS further estimated that the total undiscounted perpetual cost over a 10-year period for the final rule (starting in year three), would result in \$477 million. Finally, HHS estimated the total costs to health IT developers to be \$914 million and the total costs to HHS’s Office of the National Coordinator for Health Information Technology (ONC) to be between \$56,800 and \$113,600.

HHS estimated the total annual benefit for the final rule would be on average \$1.0 billion. HHS further estimated the total undiscounted perpetual annual net benefit for this final rule (starting in year three), would be \$124 million.

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

HHS certified that the 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 the estimated potential cost effects of the final rule reach the statutory threshold. However, HHS does not believe the final rule imposes unfunded mandates on state, local, and tribal governments, or the private sector.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO’s major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: “the Act does not apply to this rule because it does not increase direct spending; the Act does not

apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies*, Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

In its submission to us, HHS did not discuss the Act.

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

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

On April 18, 2023, HHS promulgated a proposed rule. 88 Fed. Reg. 23746 (Apr. 18, 2023). HHS stated that it received multiple comments on the proposed rule, and it responded to them in the final rule.

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

In its submission to us, HHS indicated that the final rule does not contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995.

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that OMB's Office of Information and Regulatory Affairs determined the final rule is significant under the Order. Accordingly, HHS stated that it prepared an RIA pursuant to the Order.

Executive Order No. 13132 (Federalism)

HHS stated that nothing in the final rule imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications.