U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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November 16, 2026

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

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

Subject: *Department of Health and Human Services: Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity*

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) entitled "Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity" (RIN: 0955-AA09). We received the rule on October 28, 2026. It was published in the *Federal Register* on October 28, 2026. 91 Fed. Reg. 67916. The effective date of the rule is December 28, 2026, except for amendatory instructions 7, 10, and 12 which are effective January 1, 2027. The incorporation by reference of certain material listed in the rule was approved by the Director of the *Federal Register* between February 12, 2010, and October 1, 2025.

This rule focuses on deregulatory actions identified in HHS regulations regarding health information technology standards, implementation specifications, and certification criteria and regarding certification programs for health information technology. According to HHS, the rule reduces burden, offers flexibility to both developers and providers, and supports innovation through the removal and revision of certain certification criteria and deregulatory provisions.

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 me at (202) 512-8156.

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
ENTITLED
"HEALTH DATA, TECHNOLOGY, AND INTEROPERABILITY:
ONC DEREGULATORY ACTIONS TO UNLEASH PROSPERITY"
(RIN: 0955-AA09)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) prepared an analysis of the costs and benefits for this rule. 91 Fed. Reg. 67916, 67978–67990 (Oct. 28, 2026). HHS stated that it does not expect costs to be associated with the rule, but did estimate the costs to review the rule to be $1,293,508. *Id.* at 67980. HHS estimated the total cost savings of the rule to be $1.55 billion in present value and $108.1 million in annualized cost savings in 2024 dollars and discounted at a rate of seven percent, beginning in 2027 and in perpetuity. *Id.* at 67989.

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

HHS stated that with the exception of rule review costs, this rule is deregulatory and does not create new requirements on developers of certified health IT, including small businesses. 91 Fed. Reg. at 67991.

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

According to HHS, this rule does not impose unfunded mandates on state, local, or tribal governments, or the private sector. 91 Fed. Reg. at 67991.

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

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

On December 29, 2025, HHS published a proposed rule. 90 Fed. Reg. 60970. HHS stated that for purposes of this rule, it has reviewed and responded to comments on a narrowed set of proposals from the proposed rule. 91 Fed. Reg. at 67917. According to HHS, comments received in response to other proposals from the proposed rule not discussed in the rule remain under review and consideration. *Id.* The proposed rule proposals not discussed in the rule may, in the future, be included in subsequent final rules or as revised proposals in subsequent proposed rules. *Id.*

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

HHS determined that this rule contains no new information collection requirements under the Act. 91 Fed. Reg. at 67976–77.

Statutory authorization for the rule

HHS promulgated this rule pursuant to title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009; the Health Information Technology for Economic and Clinical Health Act; and the 21st Century Cures Act.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that this rule is significant under section 3(f)(1) of the Order. 91 Fed. Reg. at 67978.

Executive Order No. 13132 (Federalism)

According to HHS, nothing in this finalized rule imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications. 91 Fed. Reg. at 67991. HHS stated that it is not aware of any state laws or regulations that are contradicted or impeded by any of the policies in the rule. *Id.*