



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

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November 1, 2016

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

The Honorable Fred Upton  
Chairman  
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: ONC Health IT Certification Program: Enhanced Oversight and Accountability*

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 "ONC Health IT Certification Program: Enhanced Oversight and Accountability" (RIN: 0955-AA00). We received the rule on October 14, 2016. It was published in the *Federal Register* as a final rule on October 19, 2016. 81 Fed. Reg. 72,404.

This final rule finalizes modifications and new requirements under the ONC Health IT Certification Program, including provisions related to the Office of the National Coordinator for Health Information Technology's (ONC) role in the Program. The final rule creates a regulatory framework for ONC's direct review of health information technology (health IT) certified under the program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the program and suspending and terminating certifications issued to Complete Electronic Health Records and Health IT Modules. The final rule also sets forth processes for ONC to authorize and oversee accredited testing laboratories. In addition, it includes provisions for expanded public availability of certified health IT surveillance results.

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. Our review of the procedural steps taken indicates that HHS complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer  
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas  
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  
“ONC HEALTH IT CERTIFICATION PROGRAM:  
ENHANCED OVERSIGHT AND ACCOUNTABILITY”  
(RIN: 0955-AA00)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) presented its estimates of the costs and benefits of this final rule. HHS identified and estimated the potential monetary costs of this final rule for health IT developers, the Office of the National Coordinator of Health Information Technology (ONC), ONC-Authorized Testing Laboratories (ONC-ATLs), and health care providers. HHS categorized and addressed costs as follows: (1) costs for health IT developers to correct non-conformities identified by ONC; (2) costs for ONC and health IT developers related to an ONC inquiry into certified health IT non-conformities and ONC direct review, including costs for the new “proposed termination” step; (3) costs for health IT developers and ONC associated with the appeal process following a suspension/termination of a Complete Electronic Health Record's (EHR's) or Health IT Module's certification; (4) costs for health care providers to transition to another certified health IT product when the certification of a Complete EHR or Health IT Module that they currently use is terminated; (5) costs for ONC-ATLs and ONC associated with ONC-ATL accreditation, application, renewal, and reporting requirements; (6) costs for ONC-ATLs and ONC related to revoking ONC-ATL status; and (7) costs for ONC-Authorized Certification Bodies (ONC-ACBs) to publicly report (submit) identifiable surveillance results to the Certified Health IT Product List (CHPL). HHS also provided an overall annual monetary cost estimate for this final rule. HHS rounded all estimates to the nearest dollar and expressed all estimates in 2016 dollars. HHS estimated the overall annual cost for this final rule, based on the cost estimates outlined above, will range from \$171,011 to \$650,352,050 with an average annual cost of \$6,597,033.

HHS did not have available means to quantify the benefits of this final rule, but believes there are many qualitative benefits. According to HHS, this final rule's provisions for ONC direct review of certified health IT promote health IT developers' accountability for the performance, reliability, and safety of certified health IT, and facilitate the use of safer and reliable health IT by health care providers and patients. Specifically, ONC's direct review of certified health IT will facilitate ONC's assessment of non-conformities and ability to require comprehensive corrective actions for health IT developers to address non-conformities determined by ONC, including notifying affected customers. According to HHS, if ONC ultimately suspends and/or terminates a certification issued to a Complete EHR or Health IT Module under the processes established in this final rule, such action will serve to protect the integrity of the program, patients, and users of health IT. Additionally, according to HHS, this final rule's provisions will also provide other benefits. Specifically, ONC's authorization and oversight of testing labs will promote further public confidence in testing and certification by facilitating ONC's ability to timely and directly address testing issues for health IT. The public availability of identifiable surveillance results will enhance transparency and the accountability of health IT developers to their customers. Further, the public availability of identifiable surveillance results will likely benefit health IT

developers by providing a more complete context of surveillance in the certified health IT industry by illuminating good performance and the continued conformity of certified health IT with program requirements. Overall, HHS believes this final rule will improve program conformity as well as further public confidence in certified health IT.

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

HHS certified 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 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 2, 2016, HHS published a proposed rule. 81 Fed. Reg. 11,056. HHS received comments on the proposed rule which it discussed in the final rule.

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

HHS determined that this final rule contains information collections requirements under the Act. Under the ONC Health IT Certification Program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC-AA) must submit certain information, organizations that wish to become an ONC-ACB must comply with collection and reporting requirements, and ONC-ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results. For the final rule, HHS estimated the annualized total burden to be 128 hours, which reflects an increase from the estimate in the proposed rule.

Statutory authorization for the rule

HHS promulgated this rule under the authority of sections 300jj-11 and 300jj-14 of title 42 and section 552 of title 5, United States Code.

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

HHS determined that this final rule is an economically significant rule under the Order as the potential costs associated with this final rule could be greater than \$100 million per year. This rule was submitted to OMB for review.

Executive Order No. 13,132 (Federalism)

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