



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

### **45 CFR Parts 170 and 171**

### **RIN 0955-AA01**

## **21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program**

**AGENCY:** Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** On March 4, 2019, the Department of Health and Human Services (HHS) published a proposed rule that would implement 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. The comment period for the rule was scheduled to close on May 3, 2019. This document extends the comment period for the proposed rule by 30 days to June 3, 2019.

**DATES:** The comment period for the proposed rule published March 4, 2019, at 84 FR 7424, is extended. Comments must be received on or before June 3, 2019.

**ADDRESSES:** You may submit comments, identified by RIN 0955–AA01, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

*Enhancing the Public Comment Experience:* To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format on ONC's website (<http://www.healthit.gov>). We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a

separate document (“public comment template”) is available on ONC’s website (<http://www.healthit.gov>) for the public to use in providing comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on proposals and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages. We believe that use of the document may facilitate our review and understanding of the comments received.

*Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person’s social security number; date of birth; driver’s license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection)..

**FOR FURTHER INFORMATION CONTACT:** Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

**SUPPLEMENTARY INFORMATION:** In the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” proposed rule that appeared in the March 4, 2019 **Federal Register** (84 FR 7424), we solicited public comments on proposals to implement 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. The comment period for the rule was scheduled to close on May 3, 2019. This document extends the comment period for the proposed rule by 30 days until June 3, 2019.

To date, we have received comments from organizations with broad stakeholder representation requesting that we extend the 60-day comment period for the proposed rule. For example, we have received comments requesting more time from clinicians, hospitals, health IT developers and developer associations, professional societies, researchers, quality improvement organizations, health plans, and patient advocacy organizations. The commenters have stated that due to the depth and complexity of the policies proposed, it is critical for the public to have extended time in providing sufficient and thoughtful comments to advance shared goals and shape the interoperability landscape. Based on these public comments and the stated goals of the proposed rule to improve interoperability and patient access to health information for the purposes of promoting competition and better care, we are extending the comment period for the proposed rule for an additional 30 days.

Dated: April 18, 2019.

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**Alex M. Azar II,**

Secretary,

Department of Health and Human Services.

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