

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485

[CMS-9115-N]

RIN 0938-AT79

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers; Supplement and Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule; supplement and extension of comment period.

SUMMARY: This document extends the comment period for the proposed rule entitled “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers” that appeared in the March 4, 2019 *Federal Register*. The comment period for the proposed rule, which would end on May 3, 2019, is extended 30 days to June 3, 2019. We additionally note that based on public comments received on this proposed rule, we will adjust the effective dates of our policies to allow for adequate implementation timelines, as appropriate.

DATES: The comment period for the proposed rule (84 FR 7610) is extended to 5 p.m., eastern daylight time, on June 3, 2019.

ADDRESSES: You may submit comments as outlined in the March 4, 2019 proposed rule (84 FR 7610). Please choose only one method listed.

FOR FURTHER INFORMATION CONTACT: Alexandra Mugge, (410) 786-4457, for issues related to interoperability, CMS health IT strategy, technical standards and patient matching.

Natalie Albright, (410) 786-1671, for issues related to Medicare Advantage.

John Giles, (410) 786-1255, for issues related to Medicaid.

Emily Pedneau, (301) 492-4448, for issues related to Qualified Health Plans.

Meg Barry, (410) 786-1536, for issues related to CHIP.

Thomas Novak, (202) 322-7235, for issues related to trust exchange networks and payer to payer coordination.

Sharon Donovan, (410) 786-9187, for issues related to federal-state data exchange.

Daniel Riner, (410) 786-0237, for issues related to Physician Compare.

Ashley Hain, (410) 786-7603, for issues related to hospital public reporting.

Melissa Singer, (410) 786-0365, for issues related to provider directories.

CAPT Scott Cooper, USPHS, (410) 786-9465, for issues related to hospital and critical access hospital conditions of participation.

Lisa Bari, (410) 786-0087, for issues related to advancing interoperability in innovative models.

Russell Hendel, (410) 786-0329, for issues related to the Collection of Information or the Regulation Impact Analysis sections.

SUPPLEMENTARY INFORMATION: In the “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers” proposed rule that appeared in the March 4, 2019 *Federal Register* (84 FR 7610), we solicited public comments on proposed policies that aim to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve access to, and the quality of, information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers.

Since the issuance of the proposed rule, we have received inquiries from a variety of stakeholders, including healthcare provider organizations and industry representatives requesting an extension to the comment period. In order to maximize the opportunity for the public to provide meaningful input to CMS, we believe that it is important to allow additional time for the public to prepare comments on the proposed rule. In addition, we believe that

granting an extension to the public comment period in this instance would further our overall objective to obtain public input on the proposed provisions to move the health care ecosystem in the direction of interoperability. Therefore, we are extending the comment period for the proposed rule for an additional 30 days.

While we believe it is in the best interest of the public and our proposed policies to extend the comment period for this proposed rule, we also acknowledge that stakeholders require appropriate implementation timelines that could be impacted by this extension. Therefore, we note that based on public comments received on this proposed rule, we will adjust the effective dates of our policies to allow for adequate implementation timelines as appropriate.

Dated: April 18, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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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: 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. (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.

Alex M. Azar II,
Secretary, Department of Health and Human Services.

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