







21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING, AND THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE

Implementation of the 21st Century Cures Act and Executive Orders

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
 <p>Sec. 4001 Pediatrics</p>	<ul style="list-style-type: none"> • ONC engaged with stakeholders in the public and private sector. • ONC developed ten recommendations for the voluntary certification of health IT for pediatric care in response to the requirement set forth by Congress in Section 4001 of the Cures Act. • ONC proposes to adopt new and revised certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children. • ONC is also focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.
 <p>Sec. 4002 Conditions of Certification</p>	<ul style="list-style-type: none"> • ONC proposes an approach whereby the Conditions and Maintenance of Certification express initial and ongoing requirements for health IT developers and their certified Health IT Modules. • The Conditions of Certification with accompanying Maintenance of Certification requirements, consistent with the Cures Act, would focus on: (a) information blocking; (b) assurances; (c) communications; (d) application programming interfaces (APIs); (e) real world testing of certified health IT; and (f) attestations. • ONC proposes an enforcement approach to encourage consistent compliance with the requirements. The proposed rule outlines a corrective action process for ONC to review and take action for potential or known instances where a Condition or Maintenance of Certification requirement is not being met by a health IT developer under the ONC Health IT Certification Program.
 <p>Sec. 4003 Interoperability Definition</p>	<ul style="list-style-type: none"> • ONC proposes that interoperability means, with respect to health IT, such health IT that: (1) enables the secure exchange of electronic health information (EHI) with, and use of EHI from, other health IT without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (3) does not constitute information blocking. • The proposed definition is consistent with the Cures Act interoperability definition.
 <p>Sec. 4004 Information Blocking</p>	<ul style="list-style-type: none"> • ONC proposes seven categories of practices that would be considered reasonable and necessary that, provided certain conditions are met, would not constitute information blocking. These categories were developed based on feedback from stakeholders and consultation with appropriate federal agencies. • If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy an exception, the actions would not be treated as information blocking and the actor would not be, as applicable, subject to civil penalties or other disincentives under the law.

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 <p>Sec. 4005 Exchange with Registries</p>	<ul style="list-style-type: none"> • ONC's proposed rule includes a Request for Information (RFI) on how a standards-based API might support improved information exchange between a health care provider and a registry in support of public health reporting, quality reporting, and care quality improvement. • Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.
 <p>Sec. 4006 Patient Access</p>	<ul style="list-style-type: none"> • ONC proposes to promote policies that would ensure a patient's EHI is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent through the following proposals: United States Core Data for Interoperability (USCDI) standard; "EHI export" criterion; "standardized API for patient and population services" criterion, "data segmentation for privacy (DS4P)" criteria, "consent management for APIs" criterion; API Condition of Certification; and information blocking requirements, which include providing patients access to their EHI at no cost to them. • Patient access to their EHI would be improved through the adoption of the following proposed 2015 Edition standard and certification criteria: USCDI standard; standardized APIs for patient and population services; and EHI export.
EXECUTIVE ORDERS	ONC'S WORK IN SUPPORT OF EXECUTIVE ORDERS
 <p>Executive Order 13813 Promoting Healthcare Choice and Competition Across the United States</p>	<ul style="list-style-type: none"> • ONC's proposed rule would contribute to fulfilling Executive Order 13813 by furthering patient (and health care provider) access to EHI and supporting competition in health care markets through new tools to access EHI and policies to address the hoarding of EHI. • ONC's proposed rule calls on the health care industry to adopt standardized APIs, which would allow individuals to securely and easily access structured EHI using new and innovative applications for smartphones and other mobile devices. • The proposed rule would establish information blocking provisions, focusing on improving patient and health care provider access, exchange, and use of EHI.
 <p>Executive Orders 13771 & 13777 Reducing Regulation and Controlling Regulatory Costs, and Enforcing the Regulatory Reform Agenda</p>	<ul style="list-style-type: none"> • ONC reviewed and evaluated existing regulations to identify ways to reduce burden and implement deregulatory actions. • ONC proposes potential deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. These six deregulatory actions are: (1) removal of a threshold requirement related to randomized surveillance; (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR); (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Certification Program; (4) removal of certain 2015 Edition certification criteria; (5) removal of certain Certification Program requirements; and (6) recognition of relevant Food and Drug Administration (FDA) certification processes with a request for information on the potential development of new processes for the ONC Health IT Certification Program.