

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



# Deregulatory Actions

Since the inception of the ONC Health IT Certification Program, ONC has aimed to implement and administer the ONC Health IT Certification Program in the least burdensome manner that supports our policy goals. Throughout the years, we have worked to improve the ONC Health IT Certification Program with a focus on ways to:



REDUCE BURDEN



OFFER FLEXIBILITY TO BOTH  
DEVELOPERS AND PROVIDERS



SUPPORT INNOVATION

## EXECUTIVE ORDERS



In 2017, the President issued **Executive Orders 13771** and **13777** that require agencies to identify deregulatory actions and establish a process by which agencies review and evaluate existing regulations and make recommendations for repeal or simplification.



## UPDATES TO THE ONC HEALTH IT CERTIFICATION PROGRAM

ONC has reviewed and evaluated existing ONC Health IT Certification Program regulations to identify ways to further reduce administrative burden, to implement deregulatory actions through guidance, and to propose potential new deregulatory actions in the proposed rule that will reduce burden for health IT developers, health care providers, and other stakeholders.

**This can be accomplished through six deregulatory activities:**

1. Removal of Randomized Surveillance Requirements
2. Removal of the 2014 Edition from the Code of Federal Regulations
3. Removal of the ONC-Approved Accreditor (ONC-AA) from the ONC Health IT Certification Program
4. Removal of Certain 2015 Edition Certification Criteria and Standards
5. Removal of Certain Program Requirements
6. Recognition of Food and Drug Administration (FDA) Processes



### 1. Removal of Randomized Surveillance Requirements

ONC-ACBs are required to conduct surveillance of certified health IT under the ONC Health IT Certification Program to ensure that health IT continues to conform and function as required by the full scope of the certification requirements. On September 21, 2017, we exercised enforcement discretion with respect to the implementation of randomized surveillance by ONC-ACBs. We are now considering eliminating certain regulatory randomized surveillance requirements and changing the requirement that ONC-ACBs must conduct in-the-field, randomized surveillance, to specify that ONC-ACBs *may* conduct in-the-field, randomized surveillance.



Stakeholders have expressed concern that the benefits of in-the-field, randomized surveillance may not outweigh the time commitment required by providers, particularly if non-conformities are not found. The removal of randomized surveillance requirements would also give ONC-ACBs more time to focus on other priorities.

## 2. Removal of the 2014 Edition from the Code of Federal Regulations



The removal of the 2014 Edition from the Code of Federal Regulations (CFR) would make the 2015 Edition the baseline for health IT certification. Removal of the 2014 Edition would eliminate inconsistencies and costs caused by health IT certification and implementation of two different editions with different functionalities and versions of standards.

Patient care could improve through the reduced risk of error that comes with the health care system's consistent implementation and use of health IT certified to the 2015 Edition. Innovation could also improve with health IT developers (including third-party software developers) developing to only one set of newer standards and implementation specifications, which would be more predictable and less costly. Further, maintaining only the 2015 Edition would reduce the cost and burden for health IT developers, ONC-ACBs, and ONC-ATLs because they would no longer have to support two increasingly distinct sets of requirements.

## 3. Removal of the ONC-Approved Accreditor (ONC-AA) from the ONC Health IT Certification Program



The ONC-AA's role is to accredit certification bodies for the ONC Health IT Certification Program and to oversee the ONC-ACBs. However, years of experience and changes with the Program have led ONC to conclude that, in many respects, the role of the ONC-AA to oversee ONC-ACBs is now duplicative of ONC's direct oversight. More specifically, ONC's experience with administering the Principles of Proper Conduct for ONC-ACBs, as well as issuing necessary regulatory changes, has demonstrated that ONC, on its own, has the capacity to provide the appropriate oversight of ONC-ACBs. Therefore, we believe removal of the ONC-AA would reduce the ONC Health IT Certification Program's administrative complexity and burden.

## 4. Removal of Certain 2015 Edition Certification Criteria and Standards

ONC reviewed and analyzed the 2015 Edition Certification Criteria to determine whether there are certification criteria we could remove. We have identified both criteria and standards for removal. We believe the removal of these criteria and standards will reduce burden and costs for health IT developers and health care providers by eliminating the need to: design and meet specific certification functionalities; prepare, test, and certify health IT in certain instances; adhere to associated reporting and disclosure requirements; maintain and update certifications for certified functionalities; and participate in surveillance of certified health IT.

### Removed Criteria

<b>2015 Base EHR Definition Criteria</b>	x Problem list (§ 170.315(a)(6))	x Medication allergy list (§ 170.315(a)(8))
	x Medication list (§ 170.315(a)(7))	x Smoking status (§ 170.315(a)(11))
<b>Other Criteria</b>	x Drug formulary and preferred drug list checks (§ 170.315(a)(10))	x Common Clinical Data Set summary record – receive (§ 170.315(b)(5))
	x Patient-specific education resource (§ 170.315(a)(13))	x Secure messaging (§ 170.315(e)(2))
	x Common Clinical Data Set summary record – create (§ 170.315(b)(4))	

## 5. Removal of Certain ONC Health IT Certification Program Requirements



We propose to remove certain mandatory disclosure requirements and a related attestation requirement. The disclosure requirements regarding certified health IT limitations are no longer necessary given the Cures Act information blocking provision and Conditions of Certification, which we are implementing with the proposed rule. We believe removal of these requirements will reduce costs and burden for ONC Health IT Certification Program stakeholders, particularly health IT developers and ONC-ACBs.

## 6. Agreement to Recognize Food and Drug Administration Processes

Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, required that the Food and Drug Administration (FDA), in consultation with ONC and the Federal Communications Commission (FCC) develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.



In 2017, FDA announced a voluntary Software Precertification (Pre-Cert) Pilot Program as part of a broader Digital Health Innovation Action Plan. It was developed to create a tailored approach for recognizing the unique characteristics of digital technology by looking first at the firm, rather than reviewing each product, as is currently done for traditional medical products. ONC believes that health IT developers that go through a finalized Software Pre-Certification Pilot Program and present health IT for certification under the Program could qualify for, and benefit from, further efficiencies under the Program.