

CURES ACT FINAL RULE

2015 Edition Cures Update Overview

ONC’s 21st Century Cures Act Final Rule made several changes to the existing 2015 Edition Health IT Certification Criteria. The final rule introduced a small number of new certification criteria, revised several existing certification criteria, and removed several certification criteria. These changes constitute the “2015 Edition Cures Update,” which is briefly outlined below.

For more detailed information, please refer to the [2015 Edition Health Information Technology \(Health IT\) Certification Criteria](#), [2015 Edition Base Electronic Health Record \(EHR\) Definition](#), and [ONC Health IT Certification Program Modifications final rule](#), and the [21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule](#).

New Certification Criteria

The 2015 Edition Cures Update introduced two new technical certification criteria that were necessary to implement the 21st Century Cures Act. These two new certification criteria will advance interoperability between certified health IT systems and make it easier for patients to access their own electronic health information on their smartphones.

<p style="text-align: center;">§ 170.315(b)(10) Electronic Health Information (EHI) Export</p>	<p style="text-align: center;">§ 170.315(g)(10) Standardized API for Patient and Population Services</p>
<p>Focuses on the ability to export the electronic health information stored in and by certified health IT to support patient EHI access requests as well as to support a health care provider interests in exporting an entire patient population to transition to another health IT system.</p>	<p>Requires the use of the HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4 standard and several implementation specifications. Two types of API-enabled services are required —(1) services for which a single patient’s data is the focus, and (2) services for which multiple patients’ data are the focus.</p>

Two new privacy and security certification criteria adopted as part of the 2015 Edition Cures Update require transparency attestations from developers of certified health IT as part of the privacy and security certification framework.

<p style="text-align: center;">§ 170.315(d)(12) Encrypt Authentication Credentials</p>	<p style="text-align: center;">§ 170.315(d)(13) Multi-factor Authentication</p>

Revised Certification Criteria

The 2015 Edition Cures Update revised the standards referenced by several existing 2015 Edition certification criteria.

Standards Revisions

§ 170.315(b)(3) ePrescribing	§ 170.315(d)(2) Adjustable Events and Tamper-Resistance
§ 170.315(b)(7) Security Tags – Summary of Care (send) (formerly, DS4P – Send)	§ 170.315(d)(3) Audit Report(s)
§ 170.315(b)(8) Security Tags – Summary of Care (receive) (formerly, DS4P – Receive)	§ 170.315(d)(10) Auditing Actions on Health Information
§ 170.315(c)(3) CQMs – Report	

In order to advance interoperability, the 2015 Edition Cures Update also established that the data required by the United States Core Data for Interoperability (USCDI) standard be met instead of the Common Clinical Data Set. The USCDI standard establishes a set of data classes and constituent data elements required to be exchanged in support of interoperability nationwide.

USCDI Updates

§ 170.315(b)(1) Transitions of Care	§ 170.315(g)(6) Consolidated CDA Creation Performance
§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation	§ 170.315(g)(9) Application Access – All Data Request
§ 170.315(e)(1) View, Download, and Transmit to a 3rd Party	§ 170.315(g)(10) Standardized API for Patient and Population Services*
§ 170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting	

*This is a new certification criterion that also refers to the USCDI.

Removed and Time-Limited Certification Criteria

Throughout the years, ONC has worked to improve the ONC Health IT Certification Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation. To that end, as part of the 2015 Edition Cures Update, several 2015 Edition certification criteria have been removed because they will no longer support specific measures within the CMS Medicare and Medicaid Promoting Interoperability programs. Some of these certification criteria will be removed immediately, some as they are replaced by new criteria, and still others will be permitted for certification up until the Medicaid Promoting Interoperability program sunsets on January 1, 2022. We continue to believe the functionalities expressed by these criteria are essential to clinical care and will not be removed from health IT systems just because there is no longer ONC certification for them.

Criteria	Removal Date
§ 170.315(a)(6) Problem List	At effective date
§ 170.315(a)(7) Medication List	At effective date
§ 170.315(a)(8) Medication Allergy List	At effective date
§ 170.315(a)(10) Drug-formulary & Preferred Drug List	January 1, 2022 (sunset of Medicaid PI program)
§ 170.315(a)(11) Smoking Status	At effective date
§ 170.315(a)(13) Patient-specific Education Resource	January 1, 2022 (sunset of Medicaid PI program)
§ 170.315(b)(4) CCDS - Create	At effective date
§ 170.315(b)(5) CCDS - Receive	At effective date
§ 170.315(b)(6) - Data Export	December 31, 2023
§ 170.315(e)(2) Secure Messaging	January 1, 2022 (sunset of Medicaid PI program)
§ 170.315(g)(8) Application Access - Data Category Request	December 31, 2022