ONC | HealthIT
CERTIFICATION PROGRAM

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. **As of January 1, 2023, certification to § 170.315(b)(10) is the only requirement that has yet to go into effect related to Certification Program requirements outlined in ONC's 21st Century Cures Act Final Rule.**

§ 170.315(b)(10)
Electronic Health Information (EHI) export

Focuses on the ability to export EHI stored in Certified Health IT to support patient EHI access requests as well as health care provider interests in exporting the EHI of an entire patient population to another health IT system. Any Certified Health IT Module that is part of a product that electronically stores EHI must certify to the § 170.315(b)(10) EHI export criterion and make it available to consumers by December 31, 2023.

§ 170.315(g)(10)
Standardized API for patient and population services

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.

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.

§ 170.315(d)(12)
Encrypt authentication credentials

§ 170.315(d)(13)
Multi-factor authentication

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(b)(7) Security tags – summary of care - send (formerly, DS4P – Send)
§ 170.315(b)(8) Security tags – summary of care - receive (formerly, DS4P – Receive)
§ 170.315(c)(3) CQMs – report
§ 170.315(d)(2) Adjustable events and tamper-resistance
§ 170.315(d)(3) Audit report(s)
§ 170.315(d)(10) Auditing actions on health information

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. Updates to the C-CDA Companion Guide also support USCDI with the efficient transmission of C-CDA documents, and the Cures Update Final Rule required updates to the newer C-CDA

USCDI Updates
§ 170.315(b)(1) Transitions of care
§ 170.315(b)(2) Clinical information reconciliation and incorporation
§ 170.315(e)(1) View, download, and transmit to a 3rd party
§ 170.315(f)(5) Transmission to public health agencies – electronic case reporting
§ 170.315(g)(6) Consolidated CDA creation performance
§ 170.315(g)(9) Application access – all data request
§ 170.315(g)(10) Standardized API for patient and population services*

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

C-CDA Companion Guide Updates
§ 170.315(b)(1) Transitions of care
§ 170.315(b)(2) Clinical information reconciliation and incorporation
§ 170.315(b)(9) Care plan
§ 170.315(e)(1) View, download, and transmit to a 3rd party
§ 170.315(f)(5) Transmission to public health agencies – electronic case reporting
§ 170.315(g)(6) Consolidated CDA creation performance
§ 170.315(g)(9) Application access – all data request

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.

C-CDA Companion Guide Updates	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

Standards Version Advancement Process (SVAP)

The ONC Cures Act Final Rule established SVAP, which permits Certified Health IT developers to voluntarily update their Certified Health IT to newer versions of HHS Secretary-adopted standards. SVAP encourages technological advances to reach providers, patients, and other end-users more efficiently and more quickly. SVAP provides for the ongoing maintenance of Certified Health IT to incorporate new versions, supporting more rapid advancement of interoperability between federal rulemakings. Utilizing the SVAP process, the ONC Health IT Certification Program is better able to maintain pace with evolving industry standards while facilitating the availability of technological advancements used by patients, providers, and other end users.

For more information regarding process, please visit the Standards Version Advancement Process webpage which provides an in-depth overview of the process, approved standards, and regulatory citations.
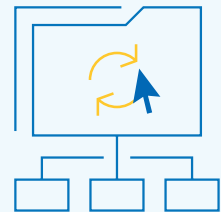
Conditions and Maintenance of Certification

As outlined in the 2015 Edition Cures Update, Certified Health IT developers must adhere to Conditions and Maintenance of Certification requirements. These requirements apply to the actions and behaviors of Certified Health IT developers as well as their Certified Health IT Modules. There are currently six Conditions and Maintenance of Certification requirements:

- Information Blocking
- Assurances
- Communications
- Application Programming Interfaces
- Real World Testing
- Attestations

Information Blocking

As part of the Information Blocking Condition of Certification, Certified Health IT developers are responsible for ensuring that all of their health IT and related actions do not constitute information blocking or inhibit the appropriate access, exchange, and use of electronic health information (EHI). For more information about this requirement, please refer to the Condition of Certification: Information Blocking Fact Sheet and the Information Blocking CCG.

Assurances

Certified Health IT developers must provide semiannual assurances via attestation that they will not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the full scope of the technology's certification. Within, on, and after December 31, 2023, Certified Health IT developers that meet applicable requirements must provide their customers with health IT certified to the § 170.315(b)(10) Electronic Health Information export certification criterion. For more information, please review the Assurances Certification CCG.

Communications

The Communications Condition requires that Certified Health IT developers be transparent about the functionality of their certified health IT while also protecting their business interests. Providers can be assured that information regarding Certified Health IT is not altered, withheld or otherwise influenced by the technology's developer when shopping the health IT marketplace.

Certified Health IT developers are required to not prohibit or restrict communications about the following aspects of the performance of health IT and related business practices:

- The usability of its health IT
- The interoperability of its health IT
- The security of its health IT
- Relevant information regarding user's experiences when using its health IT
- The business practices of Certified Health IT developers related to the exchange EHI
- The manner in which a user of health IT has used such technology

The Communications Condition of Certification promotes enhanced transparency related to the business practices of Certified Health IT developers and the functionality of their Certified Health IT Modules while simultaneously protecting the business interests of the developer and related entities. This requirement also protects the rights of users and other stakeholders including researchers, patients, and industry groups by ensuring open communication regarding Certified Health IT free from interference from the associated health IT developer. Certified Health IT developers are required to send notices annually informing customers and others with whom they have contracts or agreements containing provisions contravening this Condition they will not be enforcing those provisions, up until they are removed or amended. Additionally, Certified Health IT developers cannot establish, renew, or enforce contracts violating this Condition. For more information, please review the Communications CCG.

Application Programming Interfaces (API)

The Application Programming Interfaces (API) Condition and Maintenance of Certification requires Health IT developers with Health IT Modules certified to any certification criteria adopted in § 170.315(g)(7) through (g)(10) to:

1. Publish APIs and allow health information from such technology to be accessed, exchanged, and used without special effort.

2. Publish complete business and technical documentation, via a publicly accessible hyperlink.

3. Publish all terms and conditions for its certified API technology including material information and API fees.

4. Abide by permitted/prohibited API fees and keep for inspection detailed records of any fees charged with respect to the certified API technology.

5. Abide by openness and pro-competitive conditions.

Together, these requirements will enable Certified Health IT developers to integrate a wider array of technologies into their functional scope, as well as help providers transmit EHI through different technologies without having to worry about excess fees and/ or restrictions. For patients, these requirements will support their ability to efficiently access to their EHI through the use of an API technology of their choice. For more information, please review the API Resource Guide.

Real World Testing

The Real World Testing Condition and Maintenance of Certification requires Health IT developers with one or more Health IT Module(s) certified to any of the certification criteria outlined in 45 CFR 170.405(a) must successfully test the real world use of those Certified Health IT Modules. Real World Testing is a process by which Certified Health IT developers publicly demonstrate the interoperability and functionality of their Certified Health IT in production settings and scenarios, rather than in a controlled test environment with an ONC Authorized Testing Lab (ONC-ATL). Real World Testing also shows how Certified Health IT developers who use newer versions of specific standards approved by ONC demonstrate conformance to these newer standards. For more information, please review the Real World Testing page of the website.

Attestations

Certified Health IT developers must attest every six months for purposes of compliance with the Conditions and Maintenance of Certification specified in 45 CFR 170.406(a). Attestations are submitted to ONC-ACBs. ONC-ACBs review submissions for completion and share the Certified Health IT developers' attestations with ONC. Attestations are made publicly available through the CHPL. For more information, please review the Attestations CCG.

More Information on the Cures Update Final Rule and related requirements can be found on the **ONC Certification Program Resources** webpage.