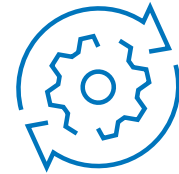


ONC HEALTH IT CERTIFICATION PROGRAM

2015 Edition Cures Update: What It Means for Certified Health IT Developers

After reviewing this fact sheet, developers will know:

- Which new certification criteria must be provided to their customers by December 31, 2022, and how this policy is different from previous editions
- Important data and standards enhancements that must be provided to their customers by December 31, 2022
- What new Conditions and Maintenance of Certification requirements will come into effect in 2022



What Is New in the 2015 Edition Cures Update?

The 2015 Edition Cures Update promotes transparency, modern standards, and enhanced health IT capabilities by fostering innovation in the health care technology ecosystem to deliver better information to patients, clinicians, and other users. It accomplishes this by including several new, revised, and removed certification criteria. For example, the 2015 Edition Cures Update includes the new § 170.315(g)(10) [Standardized API for patient and population services](#) criterion that replaces § 170.315(g)(8) Application access – data category request. This new, standards-based API will enable plug-and-play interoperability and underpin an emerging API ecosystem that will foster applications for patient access, care coordination, clinical research, public health, and population health management.

The 2015 Edition Cures Update also includes the new § 170.315(b)(10) [Electronic health information export](#) criterion that replaces § 170.315(b)(6) data export, which will enable a clinician to export all EHI of a single patient and the EHI for the clinician’s entire patient population. When implemented in 2023, this criterion will advance data portability to facilitate switching health IT systems and provide patients with complete access to all of their EHI.

Among the other notable revised requirements is § 170.315(b)(3) [Electronic prescribing](#) certification criterion as well as the following certification criteria that must be updated to support the United States Core Data for Interoperability (USCDI):

- § 170.315(b)(1): [Transitions of Care](#)
- § 170.315(b)(2): [Clinical Information Reconciliation and Incorporation](#)
- § 170.315(e)(1): [View, Download, and Transmit 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](#)

The 2015 Edition Cures Update identifies and requires the use of technical standards, including the use of both HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, and the HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide (C-CDA Companion Guide) to support the USCDI. Additional new standards include the use of NCPDP SCRIPT Standard, 2017071 for electronic prescribing and the SMART on FHIR Application Launch Framework Implementation Guide for Standardized APIs. Further details about these changes can be found in the [2015 Edition Cures Update Reference](#).

Most new and revised 2015 Edition Cures Update certification criteria must be included in a Certified Health IT Developer’s product(s) and **provided to its customers by December 31, 2022.**



Finally, the 2015 Edition Cures Update establishes new [Conditions and Maintenance of Certification requirements](#), including new requirements for Real World Testing, Application Programming Interfaces (APIs), Communications, and Attestations. These requirements apply to the actions and behaviors of Certified Health IT Developers as well as their Certified Health IT Modules. While some of the Conditions and Maintenance of Certification requirements began in 2021, several new and additional requirements will be enforced in 2022.

What to Do in 2022

2015 Cures Update Requirement	Compliance Deadline
Attestations Condition and Maintenance of Certification	April 1, 2022
Real World Testing 2023 Plans	December 15, 2022
§ 170.315(g)(10) – Standardized APIs for Patient and Population Services	December 31, 2022
§ 170.315(b)(3) Electronic Prescribing	December 31, 2022
USCDI/ Consolidated - Clinical Document Architecture (C-CDA) Companion Guide	December 31, 2022
§170.315(c)(3) Clinical Quality Measures (CQMs)	December 31, 2022
ASTM Updates	December 31, 2022
Privacy and Security Transparency Attestations	December 31, 2022
Update to Support Security Tags	December 31, 2022

New Certification Criteria in 2015 Edition Cures Update

§170.315(g)(10) Standardized API for Patient and Population Services

The [Standardized API for patient and population services \(§ 170.315\(g\)\(10\)\)](#) certification criterion requires Certified Health IT Developers to provide standardized access to single patient and multiple patient services via an API(s) using the HL7 FHIR standard. Certified APIs accelerate innovation and competition within the API marketplace while promoting information sharing among clinicians providing informed care to their patients. These applications also provide an efficient and inexpensive means to transmit EHI amongst providers and patients effectively.

The API requirements grant providers independence when selecting what third-party services to use to interact with their acquired API technology. Using integrated tracking capabilities, such as what applications their patients utilize, how often they are accessed, and what data is transmitted, providers can gain greater insight to their unique health IT needs and select products and Certified Health IT Modules accordingly.

Using certified API technology, patients gain the ability to securely access their health information using the application of their choice at no cost. Patients can also use these applications to coordinate various aspects of care, access useful information related to their care, and gain greater insight into pricing transparency.

For more information, refer to the [API Certification Companion Guide \(CCG\)](#) and the [API Resource Guide](#). The API Resource Guide is an interactive machine-readable resource intended for Certified Health IT Developers seeking ONC certification to one of the API criteria (170.315(g)(7) – (g)(10)) or compliance with API Conditions or Maintenance of Certification requirements. It is a comprehensive resource that incorporates ONC clarifications from the ONC Cures Act Final Rule preamble, Certification Companion Guides, and additional educational materials to assist Certified Health IT developers to meet the API requirements of the ONC Certification Program.

Why It's Important

- **Developers** can integrate a wider array of functionalities into their products and make available standardized data routinely available for access, exchange, and use.
- **Providers** can efficiently transmit electronic health information (EHI) amongst health IT systems and to their patients.
- **Patients** can efficiently access to their EHI through the use of an API technology, where and how they want.

What This Means for Developers

Developers of a Certified Health IT Module previously certified to the §170.315(g)(8) application access — data category request must provide their customers with Health IT Modules certified to § 170.315(g)(10) Standardized APIs for patient and population services by **December 31, 2022**.

New Certification Criteria in 2015 Edition Cures Update

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

The 2015 Edition Cures Update introduces the [EHI Export \(§ 170.315\(b\)\(10\)\)](#) certification criterion. Enforcing ONC's commitment to interoperability, this criterion promotes enhanced access to EHI for health care consumers while equipping health care providers with better tools to transmit EHI from one health IT system to another.

Health IT developers with technologies certified to this criterion will provide their customers with Health IT Modules capable of exporting single and multi-patient EHI securely and efficiently to different health IT systems. In addition, patients utilizing these technologies can easily access their EHI upon request. Certified Health IT Developers have until December 31, 2023, to deliver this capability to their customers.

Why It's Important

- **Developers** will consume more complete data from clients that move from a competitor's system and better support continuity of care for clinicians.
- **Providers** can more efficiently switch from one health IT system to another without losing EHI or having to rely on simple summary records.
- **Patients** are assured that all their EHI is readily accessible to them and their designees.

What This Means for Developers

Developers of a Certified Health IT Module that is part of certified health IT product that electronically stores EHI must certify to the § 170.315(b)(10) EHI export criterion by **December 31, 2023**.

Data and Standards Updates in 2015 Edition Cures Update

§ 170.315(b)(3) Electronic Prescribing

The use of a new standard for [electronic prescribing](#) equips Certified Health IT Modules with the ability to reliably transmit medication orders. As a result, health care providers can utilize certified health IT to transmit prescriptions to their patients' pharmacies securely and accurately. Health IT that is certified to §170.315(b)(3) improves patient safety and satisfaction through reduced transmission errors (such as incorrect prescribed dosage) and rapid prescription fulfillment.

What This Means for Developers

Health IT Developers with Health IT Modules certified to the § 170.315(b)(3) electronic prescribing criterion must update their health IT to support the use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2017071 standard by **December 31, 2022**.

Data and Standards Updates in 2015 Edition Cures Update

United States Core Data for Interoperability (USCDI) and Consolidated Clinical Data Architecture (C-CDA) Companion Guide

The [USCDI](#) is a standardized set of health data classes and constituent data elements that replaces the Common Clinical Data Set (CCDS) to enhance nationwide, interoperable health information exchange. The USCDI includes a number of new data classes and elements, such as:

- Provenance
- Pediatric Vital Signs
- Clinical Notes
- Address, Email, and Phone

The [C-CDA Companion Guide](#) will also support USCDI v1 and subsequent versions so that health care providers can efficiently transmit C-CDA documents amongst different health IT systems, and to other entities like public health agencies. Health IT Developers currently certified to the following 2015 Edition criteria have until December 31, 2022 to **provide their customers** with updated versions of their products that support USCDI and/or C-CDA standards:

- § 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 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](#)

Why It's Important

- **Developers** can more easily exchange, use, and leverage USCDI and C-CDA data received from other developers, dramatically improving interoperability.
- **Providers** can consistently and routinely transmit USCDI and C-CDA data elements across all certified health IT for patient care.
- **Patients** can more reliably access their EHI and leverage plug-and-play applications using USCDI data.

What This Means for Developers

- Health IT Developers currently certified to affected 2015 Edition certification criteria have until December 31, 2022 to **provide their customers** with updated versions of their products that support USCDI.
- Health IT Developers with Health IT Modules certified to affected 2015 Edition certification criteria must provide their customers with an updated version of the Certified Health IT Module that supports the HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 (C-CDA Companion Guide) templates by **December 31, 2022**.

Data and Standards Updates in 2015 Edition Cures Update

§170.315(c)(3) Clinical Quality Measures (CQMs)

The 2015 Edition Cures Update revised the § 170.315(c)(3) [Clinical quality measures \(CQMs\) - report](#) certification criterion to remove the HL7® Quality Reporting Document Architecture (QRDA) standard requirements and in their place require Health IT Modules to support the CMS QRDA Implementation Guides (IGs). Health IT developers are permitted to test and certify to the newest version of CMS QRDA Category I and Category III IGs regardless of the versions approved by the National Coordinator via the Standards Version Advancement Process (SVAP). While Health IT Developers are not required to re-certify to updated versions of CQMs, they must test and certify to newly added CQMs.

Why It's Important

- **Developers** will face less burden in their certification process by removing certification requirements that do not support quality reporting for CMS programs.
- **Providers** can now utilize a CMS specific QRDA IG for CMS program(s) reporting.

What This Means for Developers

Developers of affected certified health IT must have their updated certified health IT product(s) available to their customers by **December 31, 2022**.

§ 170.315(d)(2), § 170.315(d)(3), and/or § 170.315(d)(10) ASTM Updates

The 2015 Edition Cures Update revised the § 170.315(d)(2) [Auditable events and tamper-resistance](#), § 170.315(d)(3) [Audit report\(s\)](#), and the § 170.315(d)(10) [Auditing actions on health information](#) certification criteria to update to the most recent version of the standard, ASTM E2147-18. For additional information, refer to the § 170.315(d)(2) [Auditable events and tamper-resistance](#), § 170.315(d)(3) [Audit report\(s\)](#), and § 170.315(d)(10) [Auditing actions on health information](#) Certification Companion Guides (CCGs).

Why It's Important

- **Developers** can now use the most up-to-date ASTM specifications for audit and disclosure logs.
- **Providers** are able to create audit reports for specific time periods and sort entries in the audit log by a standardized set of now up to date and relevant data elements.
- **Patients** are confident in the security of their information as up-to-date standards mean better tracking for improved patient safety.

What This Means for Developers

A Health IT Developer with health IT certified to [§ 170.315\(d\)\(2\)](#), [§ 170.315\(d\)\(3\)](#), and/or [§ 170.315\(d\)\(10\)](#) prior to May 1, 2020 must have their updated certified health IT product(s) available to their customers by **December 31, 2022**.

Data and Standards Updates in 2015 Edition Cures Update

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.

Privacy and Security Criteria

The 2015 Edition Cures Update also included a number of enhancements designed to improve privacy and security of Certified Health IT. These include a new requirement at [§170.315\(d\)\(12\) Encrypt authentication credentials](#) to attest “yes” or “no” to encrypting authentication credentials and a new [§170.315\(d\)\(13\) Multi-factor authentication](#) criterion. These criteria will provide increased transparency, and if a developer attests “yes” to these criteria regarding a certified Health IT Module, that Health IT Module will then be subject to ONC-ACB surveillance for any potential non-conformity with the requirements of these criteria.

In addition, Certified Health IT Developers may update their Health IT Modules voluntarily to support security tagging at the document, section, and entry levels by **December 31, 2022**. These criteria include [§ 170.315\(b\)\(7\) security tags – summary of care - send](#) and [§ 170.315\(b\)\(8\) security Tags – summary of Care - receive](#). Certified Health IT Modules had previously been able to only support security tags at the document level.

Why It's Important

- **Developers** can certify Health IT Modules to newer versions of adopted standards.
- **Providers** can utilize more advanced technology that rely on new versions of adopted standards.
- **Patients** can access their EHI using more advanced forms of technology.

What This Means for Developers

A Health IT Developer with health IT certified to applicable criteria is permitted to update its Certified Health IT to newer, approved standards. The SVAP cycle includes a yearly comment period from January to May. Approved SVAP versions are announced in June each year and become effective for Certification Program use in August of that year.

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](#)
- [Attestations](#)
- [Real World Testing](#)
- [Assurances](#)
- [Application Programming Interfaces](#)
- [Communications](#)

Each of the Conditions and Maintenance of Certification requirements is accompanied by a Certification Companion Guide (CCG) designed to provide Certified Health IT Developers with important clarifications to help them fully understand what is required.

Information Blocking Condition of Certification

As part of the new Information Blocking Condition of Certification, Certified Health IT Developers are prohibited from information blocking. Until the **October 6, 2022** compliance date, electronic health information (EHI) for information blocking purposes is limited to the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) standard adopted in [45 CFR 170.213](#). On and after October 6, 2022, EHI is defined in [45 CFR 171.102](#). For more information about this requirement, please refer to the [Condition of Certification: Information Blocking Fact Sheet](#) and the [Information Blocking CCG](#).

Assurances Condition and Maintenance of Certification

Certified Health IT Developers must provide 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. Certified Health IT Developers must submit their attestations beginning **April 1, 2022** and semiannually thereafter. 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](#).

Attestations Condition and Maintenance of Certification

Beginning **April 1, 2022**, 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 will be submitted to ONC-ACBs. ONC-ACBs will review submissions for completion and share the Certified Health IT Developers' attestations with ONC. Attestations will be made publicly available through the CHPL. Additional information on submitting attestations will be forthcoming from ONC. For more information, please review the [Attestations Certification Companion Guide](#).

Application Programming Interfaces Condition and Maintenance of Certification

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. Certified Health IT Developers that meet the requirements outlined in the API Condition of Certification must provide their customers with API technology certified to § 170.315(g)(10) no later than **December 31, 2022**.

Real World Testing Condition and Maintenance of Certification

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.

Health IT Module(s) certified to any of the certification criteria outlined in 45 CFR 170.405(a) must have a 2023 Real World Testing Plan approved by their ONC-ACB and made publicly available on the CHPL no later than **December 15, 2022**.

The following resources will help Certified Health IT Developers to fully understand the requirements of the Real World Testing Condition and Maintenance of Certification:

1. [Real World Testing Resource Guide](#)
2. [Real World Testing–What It Means for Health IT Developers – Fact Sheet](#)
3. [Real World Testing Certification Companion Guide](#)
4. [Real World Testing Plan Template](#)
5. [Real World Testing Results Report Template](#)

Communications Condition of Maintenance of Certification

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.

As part of the new [Communications Condition of Certification](#), 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.



Questions regarding the 2015 Edition Cures Update should be submitted to your ONC-ACB or through the [ONC Health IT Feedback and Inquiry Portal](#).

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this guide is not a legal document. The official requirements are contained in the relevant laws and regulations.

