The Office of the National Coordinator for Health Information Technology

CURES ACT FINAL RULE

2015 Edition Cures Update Key Dates

The Interim Final Rule (IFR) *Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency* provides needed flexibilities to respond effectively to serious public health threats posed by the spread of the coronavirus disease 2019 (COVID-19). Recognizing the urgency of this situation, and understanding that caring for patients with COVID-19 is of utmost importance, ONC issued the IFR to extend certain compliance dates and timeframes in the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule that was published in the Federal Register on May 1, 2020 (85 FR 25642) and became effective on June 30, 2020.

June 30, 2020 (Final Rule Effective Date)

Removed from the ONC Health IT Certification Program (Program)

2014 Edition

- To finalize removal of the 2014 Edition, the following are removed:
  - The 2014 Edition certification criteria in § 170.314;
  - Terms and definitions specific to the 2014 Edition from § 170.102, including the "2014 Edition Base EHR," "2014 Edition EHR certification criteria," "Complete EHR," and "Complete EHR, 2014 Edition;" and
  - § 170.545 and other references to "Complete EHR" from the regulation text.
- The standards and implementation specifications found in §§ 170.200, 170.202, 170.204, 170.205, 170.207, 170.210, and 170.299 that are referenced only in the 2014 Edition certification criteria are also removed. Adopted standards that are also referenced in the 2015 Edition, as modified by this Final Rule, remain in the CFR.
- The Common Clinical Data Set (CCDS) definition in § 170.102 is retained, but references to the standards and implementation specifications specific to the 2014 Edition are removed.

ONC-Approved Accreditor (ONC-AA)

- The ONC-AA role is removed to reduce the Program's administrative complexity and burden.

Two Percent Randomized Surveillance Requirement performed by the ONC-Authorized Certification Bodies (ONC-ACBs)

- § 170.556(c) is revised to specify that ONC-ACBs may conduct in-the-field, randomized surveillance.
- § 170.556(c)(2), which specifies that ONC-ACBs must conduct randomized surveillance for a minimum of two percent of certified health IT products per year, is removed.
- The requirement that ONC-ACBs make a good faith effort to complete randomized surveillance and the circumstances permitted for exclusion from the requirement found in § 170.556(c)(5) is removed.
- § 170.556(c)(6), which prohibited ONC-ACBs from selecting a certified health IT for randomized surveillance more than once during a 12-month period, is removed.

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2015 Edition Cures Update Key Dates

June 30, 2020 (Final Rule Effective Date)

Removed from the ONC Health IT Certification Program (cont.)

Base EHR Removal: § 170.315(b)(6) Data Export

- As of the Final Rule effective date, this criterion is removed from the 2015 Edition Base EHR definition. However, Health IT Developers may still certify to this criterion until December 31, 2023.

Disclosure of limitations requirement in § 170.523(k)(1)

- The requirement for Health IT Developers to provide detailed disclosure of material information concerning limitations that a user may encounter in implementing and using the health IT is removed. However, Health IT Developers must still provide detailed disclosure of material information concerning additional types of costs or fees in the mandatory disclosure.

Transparency attestation requirement in § 170.523(k)(2)

- The requirement for Health IT Developers to provide a transparency attestation is removed.

2015 Edition Criteria Removed

- On June 30, 2020, certain 2015 Edition certification criteria are removed from the ONC Health IT Certification Program. Removal of the following certification criteria supports burden and cost reductions for Health IT Developers and health care providers:
  - § 170.315(a)(6) Problem List
  - § 170.315(a)(7) Medication List
  - § 170.315(a)(8) Medication Allergy List
  - § 170.315(a)(11) Smoking Status
  - § 170.315(b)(4) CCDS Summary Record – Create
  - § 170.315(b)(5) CCDS Summary Record – Receive

2015 Edition Revised Criteria

- § 170.315(c)(3) Clinical Quality Measure (CQMs) – Report
  - Removed the Health Level 7 (HL7®) Quality Reporting Document Architecture (QRDA) standard requirement and replaced with the Centers for Medicare and Medicaid Services (CMS) QRDA Implementation Guide (IG). Most Health IT Modules that support annual reporting for CMS quality programs will already have implemented the CMS QRDA IG.

Annually Beginning in Calendar Year 2021

Communications Maintenance of Certification: Notice

- Health IT Developers must not impose or enforce any contractual requirement that contravenes the requirements of the Communications Condition of Certification. If Health IT Developers have contracts or agreements that contravene the requirements of this Condition of Certification, the developers must issue a written notice to all customers and those with which it has contracts or agreements containing such provisions stating that any communication or contract provision that contravenes the requirements of this Condition of Certification will not be enforced by the Health IT Developers. For more information, please review the Communications Certification Companion Guide.

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2015 Edition Cures Update Key Dates

April 5, 2021

Assurances Condition of Certification

- A Health IT Developer must 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.
  For more information, please review the Assurances Certification Companion Guide.

Communications Condition of Certification

- As part of the new Communications Condition of Certification, Health IT Developers are required to not prohibit or restrict communications about certain aspects of the performance of health IT and related business practices. Health IT Developers are able to impose certain types of limited prohibitions and restrictions that strike a balance between the need to promote open communication about health IT with the need to protect the legitimate business interests of Health IT Developers and others. For more information, please review the Communications Certification Companion Guide.

Communications Maintenance of Certification: Amend Agreements/Contracts

- If Health IT Developers have any contracts or agreements that contravene the requirements of the Communications Condition of Certification, the developers must amend their contracts/agreements in place as of June 30, 2020, to remove or void the contractual provision that contravenes the Communications Conditions of Certification requirements whenever the contract is next modified for other reasons or renewed. For more information, please review the Communications Certification Companion Guide.

Application Programming Interfaces (APIs) Condition and Maintenance of Certification

- As part of the new API Condition and Maintenance of Certification requirements finalized in § 170.404, a Certified API Developer with API technology certified to the certification criteria in § 170.315(g)(7) through (9) must comply with the API Condition of Certification requirements finalized in § 170.404(a). For more information, please review the API Certification Companion Guide.

Information Blocking Condition of Certification

- As part of the new Information Blocking Condition of Certification, Health IT Developers are prohibited from information blocking. For more information, please review the Information Blocking Certification Companion Guide.
- 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 § 171.102.

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2015 Edition Cures Update Key Dates

December 15, 2021

Real World Testing Condition and Maintenance of Certification – Initial Plans

- As part of the new Real World Testing Condition and Maintenance of Certification, Health IT Developers must successfully test the real world use of health IT for interoperability in the type(s) of setting(s) in which technology would be marketed. Real World Testing Condition and Maintenance of Certification requirements apply to Health IT Developers with one or more Health IT Module(s) certified to any one or more 2015 Edition certification criteria in:
  - § 170.315(b),
  - § 170.315(c)(1) through (3),
  - § 170.315(e)(1),
  - § 170.315(f),
  - § 170.315(g)(7) through (10), and
  - § 170.315(h).

  For more information, please refer to the 2015 Edition Cures Update Test Method for the certification criteria listed above.
- Initial Real World Testing plans must be made publicly available through the Certified Health IT Products List (CHPL) by December 15, 2021.
- Health IT Developers should check with their ONC-ACBs for deadlines to submit Real World Testing plans so that these can be published timely on the CHPL.
- For more information, please refer to the Real World Testing Certification Companion Guide.
- Additional information on submitting Real Word Testing plans will be forthcoming from ONC.

January 1, 2022

Time-Limited Criteria

- The Medicaid Promoting Interoperability Program sunsets on January 1, 2022. Therefore, certain 2015 Edition certification criteria that support measures maintained by this program will no longer be included as part of the ONC Health IT Certification Program as of January 1, 2022.
- As of January 1, 2022, an ONC-ACB may no longer issue a certification to a Health IT Module or permit continued certified status for the following certification criteria:
  - § 170.315 (a)(10) Drug Formulary and Preferred Drug List Check,
  - § 170.315 (a)(13) Patient-specific Education Resource, and
  - § 170.315(e)(2) Secure Messaging.

April 1-30, 2022

Attestations Maintenance of Certification

- Beginning in 2022, Health IT Developers must attest twice yearly for purposes of compliance with the Conditions and Maintenance of Certification requirements (except for the EHR reporting criteria submission requirement).
- Attestations will be submitted to ONC-ACBs. ONC-ACBs must review submissions for completion and share the Health IT Developers' attestations with ONC. Attestations will be made publicly available through the CHPL. The first attestation will begin April 1, 2022, and be accepted through April 30, 2022. Additional information on submitting attestations will be forthcoming from ONC.
- For more information, please review the Attestations Certification Companion Guide.

2015 Edition Cures Update Key Dates

December 31, 2022

For the following new and revised criteria, the final date for compliance is December 31, 2022. However, Health IT Developers may update some or all of the applicable criteria prior to the compliance date.

New Criteria

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

- This new criterion requires Health IT Developers to provide standardized access to single patient and multiple patient services via an API(s) using the HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 standard and several standards and implementation specifications, including the USCDI Version 1, HL7 FHIR US Core Implementation Guide STU 3.1.1, HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1), and OpenID Connect Core 1.0, incorporating errata set 1. For more information, please refer to the Standardized API for Patient and Population Services Certification Companion Guide.

Privacy and Security Transparency Attestations

- Health IT Developers must attest YES/NO for the following new certification criteria:
  - § 170.315(d)(12) Encrypt Authentication Credentials
  - § 170.315(d)(13) Multi-factor Authentication (MFA)
- These criteria require Health IT Developers to attest whether a Health IT Module supports encrypting authentication credentials and/or MFA. Neither criterion requires additional development by the Health IT Developer.

December 31, 2022

Revised Criteria

Health IT Developers who are currently certified to the 2015 Edition version of the certification criteria must update these criteria by the IFR compliance date, December 31, 2022. Details of the revised certification criteria can be found in the sections below. As of December 31, 2022, ACBs will no longer certify Health IT Modules to the 2015 Edition versions of these criteria and Health IT Developers will only be able to certify to the revised 2015 Edition Cures Update version of these certification criteria.

Update to USCDI/ Consolidated - Clinical Document Architecture (C-CDA) Companion Guide

- The USCDI replaces the CCDS and requires the following new, additional data classes and data elements:
  - Provenance;
  - Clinical Notes;
  - Pediatric Vital Signs; and
  - Address, Email, and Phone Number.
- For the period until December 31, 2022 the CCDS remains applicable for certified Health IT Modules until such Health IT Modules are updated to the USCDI.
- **USCDI Updates for C-CDA:** Health IT Developers must update their certified health IT to support the USCDI for the following criteria:
  - § 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 3rd Party;
  - § 170.315(f)(5) Transmission to Public Health Agencies — Electronic Case Reporting;
  - § 170.315(g)(6) Consolidated CDA Creation Performance; and
  - § 170.315(g)(9) Application Access — All Data Request.
- **C-CDA Companion Guide Updates:** Health IT Developers must update their certified health IT to support the HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 (C-CDA Companion Guide) templates for the following criteria:
  - § 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 3rd Party;
  - § 170.315(g)(6) Consolidated CDA Creation Performance; and
  - § 170.315(g)(9) Application Access — All Data Request.

Review the USCDI Fact Sheet to learn more. For data class descriptions and applicable standards supporting data elements, view the USCDI v1.

2015 Edition Cures Update Key Dates

December 31, 2022

Revised Criteria (cont.)

Update to Electronic Prescribing (§ 170.315(b)(3) Electronic Prescribing)

Heath IT Developers must update their health IT to support the use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2017071 standard. For more information, please review the Electronic Prescribing Certification Companion Guide.

Update to Support Security Tags

- Certification to the following criteria are voluntary. Health IT Developers can update the requirements to support security tagging at the document, section, and entry levels.
  - » § 170.315(b)(8) Security Tags – Summary of Care - Receive
- The names for these criteria are revised from the 2015 Edition as "Data Segmentation for Privacy (DS4P) Send/ Receive."

Care Plan Attestation

- Heath IT developers with health IT certified to the § 170.315(b)(9) Care Plan criterion must update to the C-CDA Companion Guide standard.

Privacy and Security Criteria

- Heath IT developers with health IT certified to § 170.315(d)(2) Auditable Events and Tamper-resistance, § 170.315(d)(3) Audit Report(s), and/or § 170.315(d)(10) Auditing Actions on Health Information must update their certified health IT to be compliant with standard ASTM E2147-18: Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems specified in § 170.210(h). The Final Rule included the requirement for Health IT Modules to support 7.1.3 Duration of Access in the ASTM E2147-18 standard. However, we have determined this requirement will not be in scope for testing and certifying to 2015 Edition Cures Update certification.

Time-Limited Criteria

§ 170.315(g)(8) Application Access – Data Category Request

- As of December 31, 2022, an ONC-ACB may no longer issue a certification to a Health IT Module or permit continued certified status for the § 170.315(g)(8) criterion.
- Health IT Developers of a certified Health IT Module previously certified to §170.315(g)(8) must by December 31, 2022 , provide its API Information Source customers with API technology certified to the certification criterion in § 170.315(g)(10) – Standardized APIs for Patient and Population Services. Please refer to the New Criteria section above.

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2015 Edition Cures Update Key Dates

March 15, 2023

Real World Testing Condition and Maintenance of Certification – Initial Results

- Real World Testing results from calendar year 2021 must be made publicly available no later than March 15, 2023.
  - » Health IT Developers should check with their ONC-ACBs for deadlines to submit Real World Testing results so that these can be published timely via a publicly available hyperlink on the CHPL.
- For more information, please refer to the Real World Testing Certification Companion Guide.
- Additional information on submitting Real Word Testing results will be forthcoming from ONC.

December 31, 2023

New Criteria

§ 170.315(b)(10) EHI Export

- This criterion is required as part of the Assurances Condition of Certification. For more information, please refer to the Assurances Certification Companion Guide.
- A Health IT Developer of a certified Health IT Module that is part of a health IT product which electronically stores EHI must certify to the certification criterion in § 170.315(b)(10).
- Requires a certified Health IT Module to electronically export all of the EHI that can be stored at the time of certification by the product of which the Health IT Module is a part. This includes exporting EHI to support single patient EHI access requests, as well as support for health care providers interested in exporting an entire patient population to transition to another health IT system.
- For more information about the § 170.315(b)(10) criterion, please refer to the EHI Export Certification Companion Guide.

Time-Limited Criteria

§ 170.315(b)(6) Data Export

- As of December 31, 2023, an ONC-ACB may no longer issue a certification to a Health IT Module or permit continued certified status for the § 170.315(b)(6) criterion.