

ONC's [Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing \(HTI-1\) Final Rule](#) implements provisions of the [21st Century Cures Act](#) and updates the [ONC Health IT Certification Program](#) (Certification Program) with new and updated standards, implementation specifications, and certification criteria. Implementation of the HTI-1 final rule's provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. Please see the [ONC HTI-1 Key Dates Fact Sheet](#) for a one-page summary of the below information.

March 11, 2024 (Final Rule Effective Date)

Remove Reference to Editions within the Certification Program

ONC first introduced the concept of an “edition” of ONC health IT certification criteria in 2012 by referencing the existing collection of criteria as the “2011 Edition EHR certification criteria” and subsequently adding the 2014 Edition, 2015 Edition, and 2015 Edition Cures Update certification criteria through rulemaking.

As described in the HTI-1 Final Rule, ONC determined that it was no longer necessary to maintain an “edition” naming convention or to adopt entirely new editions of certification criteria to update the Certification Program over time. Instead, ONC established a single set of certification criteria, which will be updated in an incremental fashion, more closely aligned with standards development cycles and regular health IT development timelines. As of the HTI-1 Final Rule effective date, all certification criteria will be referred to as simply ONC Certification Criteria for Health IT.

Real World Testing Eligible Criteria Updates

ONC adopted a certification criterion for “decision support interventions” (DSI) in 45 CFR 170.315(b)(11) which adds the DSI criterion to the list of eligible criteria for which a Certified Health IT developer must complete Real World Testing. For example, Health IT Modules certified to § 170.315(b)(11) prior to August 31, 2024, would need to, among other requirements, include this criterion in their Real World Testing plans that must be submitted by December 2024 and submit results based on those plans. Health IT Modules certified after August 31, 2024, would have until December 2025 to include the DSI criterion in their Real World Testing plans.

Base EHR Definition Updates

ONC has updated the “2015 Edition Base EHR” definition to the “[Base EHR](#)” definition, consistent with the new “editionless” Certification Program. ONC has also updated the Base EHR definition to include an option of certifying to either the § 170.315(a)(9) Clinical decision support (CDS) or the DSI criterion in § 170.315(b)(11) for the period up to and including December 31, 2024.

After December 31, 2024, the Base EHR definition will remove reference to § 170.315(a)(9) and include only § 170.315(b)(11) Decision support interventions.

Updated Criteria

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

Functionality Updates

Health IT Modules certified to § 170.315(g)(10) must be capable of revoking an authorized application's access within 1 hour of a request. This revised function in § 170.315(g)(10)(vi) for patient authorization revocation establishes in regulation a clarification issued in December 2021 stating that Health IT Modules presented for

certification are permitted to allow short-lived access tokens to expire within one hour in lieu of immediate access token revocation. All Health IT Modules certified to § 170.315(g)(10) must be able to revoke authorized application's access within 1 hour of the request as of the HTI-1 Final Rule effective date on March 11, 2024.

Criteria referencing synchronized clock standards

ONC removed current specifications for clock synchronization, which previously referenced Network Time Protocol (NTP) (Version 4 of RFC 5905) in § 170.210(g). Moving forward, ONC finalized that Health IT Modules can utilize any NTP standard that ensures time accuracy and synchronization. This standard is outlined in the following criteria:

- §170.315(d)(2) Auditable events and tamper-resistance
- §170.315(d)(3) Audit report(s)
- §170.315(d)(10) Auditing actions on health information
- §170.315(e)(1) View, download, and transmit to 3rd party

No action is required from developers that are already certified to this criterion.

December 31, 2024

Time-Limited Criteria

§ 170.315(a)(9) Clinical decision support

§ 170.315(a)(9) will expire on January 1, 2025. Any developers seeking to maintain certification to the Base EHR definition or that want to ensure continuity for customers using Health IT Modules currently certified to § 170.315(a)(9) must certify their Health IT Modules to § 170.315(b)(11) by December 31, 2024. Developers may certify to § 170.315(b)(11) as of the effective date of the HTI-1 Final Rule.

Updated Criteria

§ 170.315(b)(11) Decision support interventions

ONC has added the DSI certification criterion at § 170.315(b)(11). This criterion expands on the existing capabilities and requirements outlined in the clinical decision support certification criterion at § 170.315(a)(9), which is set to expire as of December 31, 2024. Health IT Modules wishing to satisfy requirements related to the Base EHR definition must update and provide customers with capabilities in § 170.315(b)(11) by December 31, 2024. The DSI criterion directly responds to the emergence of artificial intelligence and machine learning-based predictive decision support in health care.

§ 170.315(g)(10) Standardized API for patient and population services – Service base URLs publication

For all Health IT Modules certified to § 170.315(g)(10), and consistent with current requirements in § 170.404(b)(2), a Certified API Developer must publish, at no charge, the service base URLs and related organizational details in a standardized, FHIR-based format by December 31, 2024. This revised API Maintenance of Certification requirement will better ensure that patients have standardized access their electronic health information using applications of their choice.

December 31, 2025

Updated Criteria

USCDI Updates

ONC has updated the USCDI standard in § 170.213 by adding USCDI Version 3 (v3) and establishing a January 1, 2026, expiration date for USCDI v1 (July 2020 Errata) for purposes of the Certification Program. By December 31, 2025, any Health IT Modules seeking certification for criteria referencing § 170.213 would need to be capable of exchanging the data classes and data elements that comprise USCDI v3. This will ensure that users of Health IT Modules certified to the criteria below can consistently access, exchange, and use an expanded data set necessary for interoperability, including data related to social determinants of health, race and ethnicity, and health status, such as disability status.

Criteria cross-referencing USCDI that must be updated to USCDI v3 include:

- § 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(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

C-CDA Updates

Developers of Certified Health IT with Health IT Modules certified to criteria that reference HL7 C-CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 must update those Health IT Modules to C-CDA R2 IG Companion Guide, Release 4.1 and provide capabilities to customers by December 31, 2025. This version of the C-CDA Companion Guide supports data classes and elements included in USCDI v3.

Criteria cross-referencing C-CDA that must be updated include:

- § 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
- § 170.315(g)(9) Application access—all data request

Minimum Standards Code Set Updates

The following minimum standard code sets and accompanying certification criterion must be updated by December 31, 2025. Certified Health IT developers must attest to supporting the revised code set versions for

each certification criteria listed in their Health IT Module(s). Developers are encouraged to support the newest versions of these listed code sets and should attest "yes" if their Health IT Modules support newer versions of the revised code sets listed.

Certification Criterion	Previous Code Set	Revised Code Set
§ 170.315(a)(5) Demographics	§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	§ 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor	§ 170.207(n)(2) Sex must be coded in accordance with SNOMED CT® U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .
§ 170.315 (a)(12) Family health history	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
§ 170.315 (a)(15) Social, psychological, and behavioral data	§ 170.207(c)(3) LOINC® Database version 2.52	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
	§ 170.207(m)(1) The Unified Code for Units of Measure, Revision 1.9	§ 170.207(m)(2) The Unified Code for Units of Measure, Revision 2.1, November 21, 2017
§ 170.315 (b)(1) Transitions of care	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor	§ 170.207(n)(2) Sex must be coded in accordance with SNOMED CT® U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .
§ 170.315 (c)(4) CQM – filter	§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	§ 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(r)(1) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015	§ 170.207(r)(2) Medicare Provider and Supplier Taxonomy Crosswalk, October 29, 2021
	§ 170.207(s)(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011)	§ 170.207(s)(2) Public Health Data Standards Consortium Source of Payment Typology Code Set, December 2020, Version 9.2
§ 170.315 (f)(1) Transmission to immunization registries	§ 170.207(e)(3) HL7® Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015	§ 170.207(e)(1) HL7® Standard Code Set CVX - Vaccines Administered, updates through June 15, 2022
	§ 170.207(e)(4) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015	§ 170.207(e)(2) National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through July 19, 2022
§ 170.315 (f)(3) Transmission to public health agencies –	§ 170.207(a)(3) HTSDO SNOMED CT® International Release July 2012 and	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release

Certification Criterion	Previous Code Set	Revised Code Set
reportable laboratory tests and value/results	US Extension to SNOMED CT® March 2012 Release	
	§ 170.207(c)(2) LOINC® Database version 2.40	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
§ 170.315 (f)(4) Transmission to cancer agencies	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(c)(3) LOINC® Database version 2.52	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
§ 170.315 (f)(5) Transmission to public health agencies – electronic case reporting	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release

§ 170.315(e)(1) View, download, and transmit to 3rd party

In addition to the C-CDA and USCDI standards updates required for § 170.315(e)(1), Health IT Modules must also update functionality for this criterion by December 31, 2025. As outlined in regulation, patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in USCDI. This will give patients and their authorized representatives an electronic means to exercise their right to request a restriction granted to them by the Health Insurance Portability and Accountability Act Privacy Rule.

§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting

New requirements for Health IT Modules certified to § 170.315(f)(5) support transmission of electronic case reports to public health authorities through consensus-based, industry-developed health IT standards and implementation guides. Previously, this functionality did not reference specific health IT standards. Certified Health IT developers are allowed to certify to the existing version of this criterion's functionality until December 31, 2025. As of that date, developers must update to use either the HL7 CDA or the HL7 FHIR standards outlined in § 170.315(f)(5)(ii) and provide the updated functionality to their customers.

New code sets include:

- Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. RCTC OID: 2.16.840.1.114222.4.11.7508

New standards for use include:

- HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR)—US Realm 2.1.0—STU 2 US (HL7 FHIR eCR IG)
- HL7 CDA R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG)
- HL7 CDA R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG)

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

Health IT Modules certified to § 170.315(g)(10) must update to the following standards as of December 31, 2025:

- HL7 FHIR US Core Implementation Guide STU 6.1.0 in support of USCDI v3
- HL7 SMART Application Launch Framework Implementation Guide Release 2.0.0

Annually beginning January 2026

ONC's HTI-1 final rule created the Insights Condition and Maintenance of Certification ("Insights Condition") within the ONC Health IT Certification Program to provide transparent reporting on certified health IT. The Insights Condition's reporting will: (1) Address information gaps in the health IT marketplace; (2) Provide insights on the use of specific certified health IT functionalities; and (3) Provide information about use of certified functionalities by end users.

The reporting period is one calendar year, with 6 months provided for collating the data. Responses will be submitted annually, during the month of July. The measures and metrics are phased in over three years, with data collection starting in 2026. "Year 1" data collection starts in calendar year (CY) 2026 (January 1st, 2026-December 31st, 2026), with response submissions due in July 2027. Reporting is on an annual basis thereafter. "Year 2" measures and related metrics will begin data collection CY 2027, with reporting July 2028 (and annually thereafter). The "Year 3" measures and related metrics start data collection CY 2028, with reporting July 2029 (and annually thereafter).

Table 1: Insights Condition Measures and Metrics by Program Year

Note: “Program Year” refers to the implementation year of the Insights Condition, with the start of the data collection.

Year 1 (Data collection starts in CY 2026)

Individuals’ Access to Electronic Health Information Through Certified Health IT

- Number of unique individuals who accessed their EHI using technology certified to “standardized API for patient population services” certification criterion under § 170.315(g)(10)
- Number of unique individuals who accessed their EHI using technology certified to the “view, download, and transmit to 3rd party” certification criterion under § 170.315(e)(1)
- Number of unique individuals who accessed their EHI using any method.

Applications Supported Through Certified Health IT

- Application name(s)
- Application developer Name(s)
- Intended purpose(s) of application using categories set out in measurement specification sheets
- Intended application user(s) using categories set out in measurement specification sheets
- Application Status

Use of FHIR in Apps Through Certified Health IT

- Number of distinct certified health IT deployments (across clients) active at any time during the reporting period, overall and by user type
- Number of requests made to distinct certified health IT deployments that returned at least one FHIR resource by FHIR resource type
- Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned overall and by user type

Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT

- Number of immunizations administered overall
- Number of immunizations administered electronically submitted successfully to IISs overall

Year 2 (Data collection starts in CY 2027)**Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT**

- Number of encounters
- Number of unique patients with an encounter
- Number of unique patients with an associated C-CDA document
- Number of total C-CDA documents obtained
- Number of unique C-CDA documents obtained
- Number of total C-CDA documents obtained that were pre-processed
- Number of total C-CDA documents obtained that were not pre-processed

Use of FHIR in Apps Through Certified Health IT

- Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned by US Core Implementation Guide version

Use of FHIR Bulk Data Access Through Certified Health IT

- Number of distinct certified health IT deployments (across clients) that completed at least one bulk data access request
- Number of bulk data access requests completed (across clients) to export all data requested for patients within a specified group

Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT

- Number of immunizations administered overall by IIS and by age category
- Number of immunizations administered electronically submitted successfully to IISs overall by IIS and by age category

Immunization History and Forecasts Through Certified Health IT

- Number of immunization queries sent to IISs overall
- Number of query responses received successfully from IISs overall

Year 3 (Data collection starts CY 2028)**Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT**

- Number of total C-CDA documents obtained that were pre-processed where problems, medications, or allergies and intolerances were reconciled and incorporated via any method
- Number of total C-CDA documents obtained that were not pre-processed where problems, medications, or allergies and intolerances were reconciled and incorporated via any method
- Number of total C-CDA documents obtained that were determined to have no new problems, medications, or allergies and intolerances information by pre-processes or fully automated processes

Immunization History and Forecasts Through Certified Health IT

- Number of immunization queries sent to IISs overall by IIS
- Number of query responses received successfully from IISs overall by IIS

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Disclaimer: This fact sheet describes requirements outlined in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule. While every effort has been made to ensure the accuracy of this fact sheet, it is not a legal document. Please refer to the HTI-1 final rule for full provision details.

