

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

December 2023

Overview

In this final rule, ONC implements provisions of the 21st Century Cures Act, makes updates to the ONC Health IT Certification Program (Certification Program) including new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170, establishes a new baseline version of the United States Core Data for Interoperability (USCDI), and provides enhancements to support information sharing through updates to the information blocking regulations.

Rule Highlights



Implements the Cures Act’s “EHR Reporting Program” to require transparent reporting on different types of certified health IT metrics through the new “Insights” Condition and Maintenance of Certification.



Provides updates to the information blocking regulations in response to feedback from affected parties.



Adopts United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the baseline USCDI standard as of January 1, 2026.



Updates the Certification Program’s standards, criteria, and requirements, including:

- Standardized application programming interfaces (APIs), including adoption of the [SMART App Launch Implementation Guide v2](#);
- Electronic case reporting using HL7® Consolidated Document Architecture (CDA) and HL7 Fast Healthcare Interoperability Resources (FHIR®)-based specifications;
- A revised decision support intervention (DSI) certification criterion based on the prior clinical decision support certification criterion that includes new capabilities and transparency requirements for Health IT Modules; and
- New functionality that enables an “internet-based method” for a patient to request a restriction on the use and disclosure of their EHI.

Discontinuing Year-Themed Editions for Health IT Certification Criteria



To simplify the Certification Program and support more modular and extensible future updates, the HTI-1 final rule discontinues year-themed editions of certification criteria. This change also supports broader use of certification criteria and standards adopted by ONC for other federal agencies and programs.

Revised Standards and Criteria

Several revisions to certification criteria and standards adopted in [45 CFR Part 170](#) are also part of the HTI-1 Final Rule. The revisions in the rule will: (1) improve interoperability through more modern standards and newer versions of existing standards; (2) assist partner agencies such as CMS and the CDC in fulfilling their missions through certified health IT; (3) improve care delivery for clinicians and care experience for individuals by improving access to more interoperable data – consistently and reliably – for patient care and individual access; (4) require greater transparency regarding the decision support interventions included in certified health IT.

- **USCDI v3 Updates**

- ONC adopted USCDI v3 as a new baseline, which will coexist with USCDI v1 in the standard until USCDI v1 expires on January 1, 2026.
- ONC adopted the C-CDA Companion Guide Release 4.1 and FHIR US Core IG 6.1.0 which will coexist with existing standards until January 1, 2026.

- **Decision Support Interventions and Predictive Models**

- The “Decision Support Interventions” certification criterion has been updated and adopted as a replacement to the current criterion for CDS. This updated certification criterion includes new technical capabilities and transparency requirements for Health IT Modules, in order to improve trustworthiness and support consistency around the use of predictive algorithms or models in health care.
- The “Base EHR” definition in § 170.102 has been changed such that only the revised “Decision Support Interventions” certification criterion will satisfy the definition beginning January 1, 2025.

- **Standardized API for Patient and Population Services**

- The SMART App Launch Implementation Guide v2 was adopted to replace the SMART App Launch Implementation Guide v1 after December 31, 2025.
- The API Condition and Maintenance of Certification was updated related to [Service Base URLs](#) in order to better support patient-facing apps by requiring the use of standardized formats for “FHIR endpoints.”
- The final rule revised the requirement in [§ 170.315\(g\)\(10\)\(vi\)](#) to specify that Health IT Modules presented for certification must be able to revoke an authorized application's access at a patient's direction within one hour of the request.

- **Electronic Case Reporting**

- The [“Transmission to Public Health Agencies – Electronic Case Reporting” criterion](#) was revised to replace all functional, descriptive requirements with consensus-based, industry-developed standards and implementation guides.
- The final rule allows Health IT Modules to support either the CDA suite of implementation guides or the FHIR-based implementation guide.

- **Revised Demographics Certification Criterion**

- The final rule helps support a more inclusive health care system and has renamed the certification criterion at [§ 170.315\(a\)\(5\)](#) to “Patient Demographics and Observations,” to acknowledge that the data elements included in the criterion are now broader than just demographics information.
- The certification criterion was also updated to bring it in alignment with USCDI; replaces the terminology standards for “Sexual Orientation,” “Gender Identity,” and “Sex;” and adds new data elements for “Sex Parameter For Clinical Use,” “Pronouns,” and “Name to Use.”

- **Patient Requested Restrictions**

- The final rule revises the “View, Download, and Transmit to 3rd Party” certification criterion in § 170.315(e)(1) to require certified health IT to support an internet-based method for a patient to request a privacy restriction for any data expressed in the USCDI standards in § 170.213.

Assurances Condition and Maintenance of Certification

As a Condition of Certification requirement under the Program, health IT developers are required to provide an assurance that they will not interfere with a customer’s timely access to interoperable health IT certified under the Program. This Condition of Certification also includes two accompanying Maintenance of Certification requirements that require health IT developers to update certified Health IT Modules to all applicable revised certification criteria and provide all Health IT Modules certified to a revised certification criterion to its customers of such certified health IT within timeframes established and specified in part 170, with a 12-month timeframe for new customers.

Insights Condition and Maintenance of Certification

The [21st Century Cures Act of 2016 \(Cures Act\)](#) required ONC to establish the Electronic Health Records (EHR) Reporting Program to provide transparent reporting on certified health IT in the categories of interoperability, usability and user-centered design, security, conformance to certification testing, and more. The Cures Act also specified that a health IT developer be required to submit responses to the reporting criteria developed with respect to all certified technology offered by the health IT developer.

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 finalized Insights Condition requires a health IT developer participating in the ONC Health IT Certification Program to report on a measure if the developer has each of the following:

- 1) At least 50 hospital sites or 500 individual clinician users across their certified health IT;
- 2) Any health IT certified to the certification criteria specified in each measure; and
- 3) Any users using the certified health IT associated with the measure.

Developers of certified health IT who do not meet the qualifications above will submit a response (attestation) to indicate that they do not meet the minimum reporting qualifications for a measure.

The HTI-1 final rule adopts seven measures across four topic areas related to interoperability: individuals' access to electronic health information (EHI), public health information exchange, clinical care information exchange, and standards adoption and conformance. The measures and related criterion are listed in the table below.

AREA	MEASURE	RELATED CRITERION/ CRITERIA
Individual Access to EHI	Individuals' Access to Electronic Health Information Through Certified Health IT	§ 170.315(e)(1); § 170.315(g)(10)
Clinical Care Information Exchange	Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT	§ 170.315(b)(2)
Standards Adoption & Conformance	Applications Supported Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR in Apps Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR Bulk Data Access Through Certified Health IT	§ 170.315(g)(10)
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT	§ 170.315(f)(1)
Public Health Information Exchange	Immunization History and Forecasts Through Certified Health IT	§ 170.315(f)(1)

Please visit the [HTI-1 final rule landing page](#) to view the measure specification sheets which provide further details on the specific metrics associated with the Insights Condition measures.

Enhancements to Support Information Sharing

ONC updated definitions in the information blocking regulations in 45 CFR part 171, added new options to satisfy one of the existing exceptions, and established a new exception applicable to certain information sharing requests between parties who have chosen to become part of the Trusted Exchange Framework and Common Agreement (TEFCA). The final rule addresses feedback from interested parties about the intent and application of information blocking regulatory provisions and clarifies established regulatory terms.

Information Blocking Definitions

“Offer Health IT” – ONC defined what it means to “offer health IT” for purposes of the information blocking regulations. This definition narrows the potential applicability of the “health IT developer of certified health IT” definition through explicit exclusion of certain activities from the “offer health IT” definition.

“Health IT Developer of Certified Health IT” – ONC modified the definition of a [“health IT developer of certified health IT”](#) so that it is clear that health care providers who self-develop certified health IT would continue to be excluded from this definition if they do not offer any certified health IT to others.

“Information Blocking” – ONC revised the definition for [“information blocking”](#) to remove language that was no longer applicable. The language referred to the period of time for which electronic health information (EHI) was limited to the data elements represented in the USCDI v1, which had ended on October 5, 2023.

Information Blocking Exceptions

Infeasibility Exception

ONC revised one condition and created two new conditions for the [Infeasibility Exception](#).

- ONC revised the [“uncontrollable events” condition](#) to further clarify when an actor’s practice meets the “uncontrollable events” condition such that it would not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI.
- ONC added a new “third party seeking modification use” condition, which would apply in certain situations where the actor is asked to provide the ability for a third party (or its technology, such as an app) to modify EHI.
- ONC added a new “manner exception exhausted” condition, which is applicable when an actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners. The condition applies only under certain circumstances, including when the actor does **not** currently provide to a substantial number of individuals or entities, similarly situated to the requestor, the same requested access, exchange, or use of the requested EHI.

Manner Exception

- ONC renamed the Content and Manner Exception and renumbered its conditions to reflect removal of the “content condition” that was applicable only for the period before October 6, 2022.

TEFCA Manner Exception

ONC established a new “TEFCA Manner” Exception that applies where an actor and requestor are both part of TEFCA. Where the exception is met, fulfilling certain requests for EHI only via TEFCA will not be considered information blocking.



Visit healthit.gov/HTI-1 for additional information.