


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


April 2023


ONC seeks to implement provisions of the 21st Century Cures Act and make updates to the ONC Health IT Certification Program (Certification Program) with new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170. **The proposed rule also includes multiple requests for information (RFI)** to inform potential future rulemaking. RFI topic areas include electronic prior authorization, lab interoperability, predictive decision support interventions, and advanced Fast Healthcare Interoperability Resource (FHIR®) capabilities, among others across parts 170 and 171. We look forward to receiving public comment on these proposals and direct interested parties to the following link in order to comment healthit.gov/proposedrule.

Proposal Highlights

 Implementing the “EHR Reporting Program” to provide transparent reporting on certified health IT by establishing the Insights Condition and Maintenance of Certification.

 Providing enhancements to the information blocking regulations in response to feedback from affected parties.

 Proposing adoption of United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the standard in § 170.213 by January 1, 2025.

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

- 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 FHIR-based specifications;
- Clinical decision support (CDS) with several new transparency requirements for Health IT Modules that enable or interface with technology intended to support decision making based on predictive models or algorithms; and
- New functionality that enables a provider to flag whether specific pieces of a patient's USCDI data should be restricted from subsequent use or disclosure

Discontinuing Year-Themed Editions for Health IT Certification Criteria

To simplify the Certification Program and support more modular and extensible future updates, ONC is proposing to discontinue the year-themed editions. This change will also support broader use of certification criteria and standards adopted by ONC for other federal agencies and programs.



Revised Standards and Criteria

ONC is proposing several revisions to certification criteria and standards adopted in 45 CFR Part 170. The proposals across this section would: (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 transparency on how a predictive algorithm used for clinical decision-making is designed, developed, trained, evaluated, and should be used.

- **USCDI v3 Updates**

- ONC proposes to adopt USCDI v3 as a new baseline, which would coexist with existing requirements for USCDI v1 until it expires on January 1, 2025.
- ONC proposes to adopt the C-CDA Companion Guide Release 3* and FHIR US Core IG 5.0.1,** which would coexist with existing standards until January 1, 2025.

*It is also our understanding that HL7 is working on updating the C-CDA R2.1 Companion Guide (Release 4) for USCDI v3. If the C-CDA Companion Guide Release 4 (R4) is published before the date of publication of the final rule, it is our intention to adopt the updated Companion Guide R4 that provides guidance and clarifications for specifying data in USCDI v3.

**Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule. Therefore, it is our intention to adopt the updated US Core IG v6.0.0 that provides guidance for specifying data in USCDI v3.

- **Decision Support Interventions and Predictive Models**

- The current criterion for CDS would be renamed as the “Decision Support Interventions” certification criterion and includes several new requirements for Health IT Modules that enable or interface with technology intended to support decision-making based on predictive algorithms or models.
- The revised “Decision Support Interventions” certification criterion would improve transparency, enhance trustworthiness, and support consistency around the use of predictive algorithms or models in healthcare.
- ONC proposes changes to the “Base EHR” definition in § 170.102 such that only the revised “Decision Support Interventions” criterion would satisfy the definition beginning January 1, 2025.

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

- ONC proposes to adopt the Smart App Launch Implementation Guide v2, which would replace the Smart App Launch Implementation Guide v1 as the standard by January 1, 2025.
- ONC proposes to amend the API Condition and Maintenance of Certification requirements for Service Base URLs¹ which support patient-facing apps by identifying and requiring the use of standardized formats for FHIR endpoints.
- ONC proposes to revise the requirement in § 170.315(g)(10)(vi)² 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**

- ONC proposes to revise the “Transmission to Public Health Agencies – Electronic Case Reporting” criterion³ to adopt consensus-based, industry-developed electronic standards and implementation guides.
- The proposal would allow Health IT Modules to support either the CDA suite of implementation guides or the FHIR-based implementation guide.

- **Revised Demographics Certification Criterion**

- ONC proposes to rename § 170.315(a)(5)⁴ to “Patient Demographics and Observations,” to acknowledge that the data elements included in the criterion are broader than demographics information, as ONC looks to advance a more inclusive health care system.
- The proposal would also modify the criterion to bring it in alignment with USCDI and proposes to replace the terminology standards for “Sexual Orientation,” “Gender Identity,” and “Sex;” and add new data elements for “Sex For Clinical Use,” “Pronouns,” and “Name to Use.”

- **Patient Requested Restrictions**

- ONC proposes to adopt new requirements for certified health IT specifically in support of the HIPAA Privacy Rule’s “right to request a restriction” on uses and disclosures (see also 45 CFR 164.522(a)).
- These requirements would include a new certification criterion, an addition to ONC’s Privacy and Security Framework under the Program, and a revision to an existing criterion to support additional tools for implementing patient requested restrictions.

Assurances Condition and Maintenance of Certification

ONC proposes to require a health IT developer, as a Condition of Certification requirement under the Program, to provide an assurance that it will not interfere with a customer’s timely access to interoperable health IT certified under the Program, and includes two accompanying Maintenance of Certification requirements that require a health IT developer to update a certified Health IT Module 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 certain proposed timelines.

Insights Condition and Maintenance of Certification

The 21st Century Cures Act called for establishing an Electronic Health Record (EHR) Reporting Program to provide transparent reporting to measure the performance of certified health IT and specified that health IT developers be required, as a Condition and Maintenance of Certification requirement, to submit responses to reporting criteria in accordance with the EHR Reporting Program established. We refer to the Condition and Maintenance of Certification associated with the “EHR Reporting Program” as the “Insights” Condition and Maintenance of Certification (also referred to as the “Insights Condition”) throughout this proposed rule.

- The Insights Condition would provide transparent reporting that aims to:
 - Address information gaps in the health IT marketplace
 - Provide insights on the use of specific certified health IT functionalities
 - Provide information about consumers’ experience with certified health IT
- ONC intends for this set of proposed measures to provide insights on the interoperability category specified in the Cures Act.
- Developers of certified health IT with at least 50 hospital users or 500 clinician users would be expected to report on each applicable measure, according to the implicated certification criterion.
- Developers of certified health IT would report data related to the Insights Condition twice a year aligned with their “Attestations” Condition and Maintenance of Certification requirement (April, October submission dates), beginning April 2025.

Proposed Insights Condition Measures

- **Individual Access to Electronic Health Information**
 - Individual's Access to EHI Supported by Certified API Technology
- **Public Health Information Exchange**
 - Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT
 - Immunization History and Forecasts
- **Clinical Care Information Exchange**
 - C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism
 - C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT
- **Standards Adoption and Conformance**
 - Applications Supported Through Certified Health IT
 - Use of FHIR in Apps Supported by Certified API Technology
 - Use of FHIR Bulk Data Access through Certified Health IT
 - Electronic Health Information Export through Certified Health IT

Enhancements to Support Information Sharing

ONC proposes to update definitions for the information blocking regulations in 45 CFR part 171 and add new options to satisfy two of the existing exceptions. The proposed rule addresses feedback from interested parties seeking additional information about the intent and application of information blocking regulatory provisions and clarifies established regulatory terms.

What Information Blocking Definitions Does the Proposed Rule Address?

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

“Health IT Developer of Certified Health IT” – ONC proposes to modify the definition of a “health IT developer of certified health IT”⁵ so that it remains clear that health care providers who self-develop certified health IT for their own use would continue to be excluded from this definition if they do not offer any certified health IT to others.

“Information Blocking” – ONC proposes to revise the definition for “information blocking” to remove the period of time for which electronic health information (EHI) is limited to the data elements represented in the USCDI v1 because, as of October 6, 2022, EHI is no longer limited to the data elements represented in the USCDI v1. Because ONC included the same date in the Content and Manner Exception, ONC proposes to also revise the exception to remove the existing date as no longer necessary.

What Information Blocking Exceptions Does the Proposed Rule Address?

Infeasibility Exception

ONC proposes to revise one condition and create two new conditions for the Infeasibility Exception.

- ONC proposes to revise the “uncontrollable events” condition⁶ 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 proposes to add a new “third party seeking modification capability” condition (option), 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 proposes to add a new “manner exception exhausted” condition, which would apply where an actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners. The condition would not apply under certain circumstances, including when the actor currently provides 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 - TEFCA manner

- ONC proposes to rename the Content and Manner Exception and add a TEFCA manner condition which would acknowledge that certain agreements have been reached by parties who join TEFCA.
- The TEFCA manner condition would be available for any and all EHI and any TEFCA permitted purpose.

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1. <https://hl7.org/fhir/smart-app-launch/>
 2. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-D/section-170.404#p-170.404\(b\)\(2\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-D/section-170.404#p-170.404(b)(2))
 3. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315\(g\)\(10\)\(vi\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315(g)(10)(vi))
 4. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315\(f\)\(5\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315(f)(5))
 5. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170>
 6. <https://www.ecfr.gov/current/title-45/part-171>
 7. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-A/section-171.102#p-171.102\(Health%20IT%20developer%20of%20certified%20health%20IT\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-A/section-171.102#p-171.102(Health%20IT%20developer%20of%20certified%20health%20IT))
 8. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-B/section-171.204>
 9. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-B/section-171.204#p-171.204\(a\)\(1\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-B/section-171.204#p-171.204(a)(1))



Learn more about **Information Blocking**
For additional information about the proposed rule,
visit healthit.gov/proposedrule.

Disclaimer: This fact sheet describes select proposals described in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed 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 proposed rule for full provision details.

