



Health Data, Technology, and Interoperability (HTI-2) Proposed Rule

Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule

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- The materials contained in this presentation are based on the proposals in the “Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability” proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.
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AGENDA

- ➔ Purpose of HTI-2 Proposed Rule
- ➔ Overview of Certification Program
- ➔ New and Revised Public Health Data Exchange Certification Criteria - PDMP

Purpose of HTI-2 Proposed Rule



Implementing the 21st Century Cures Act

- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking
- Establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA



Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14036 “Promoting Competition in the American Economy”
- E.O. 14058 “Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government”



Leveraging Health IT and Advancing Interoperability

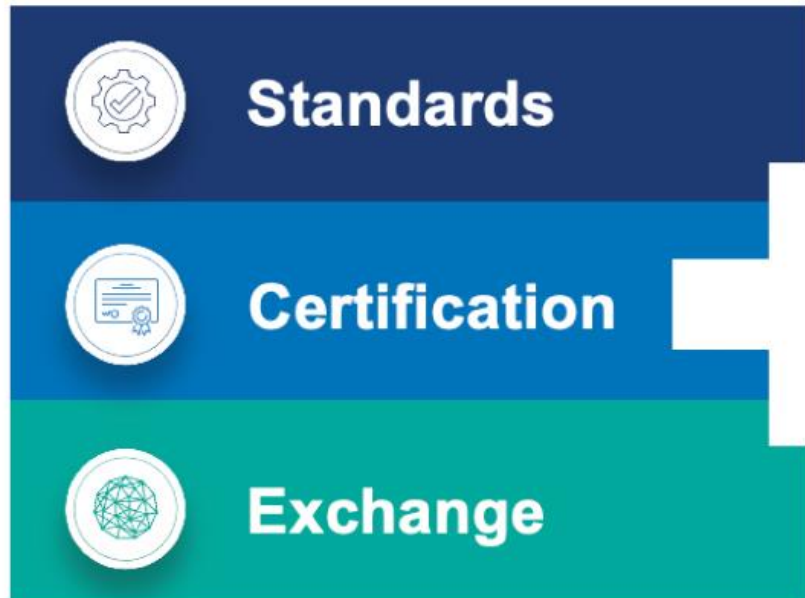
- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program



Overview of Certification Program



ONC Activities



ONC Objectives



The Policy Solution: Certification of Health IT

ONC-certified health IT is the **foundation of the US digital healthcare infrastructure**, covering **400+ health IT products** used by **96% of hospitals** and **nearly 80% of clinical offices** and required by **numerous federal programs**.

ONC Health IT Certification:

- Establishes baseline technical and standards-based capabilities
- Enables interoperability and the exchange of electronic health information
- Sets privacy and security requirements
- Promotes competition and choice in health IT marketplace
- Increases transparency in the quality and performance of certified health IT



New and Revised

Public Health Data Exchange Certification Criteria

Public Health Data Exchange- Revisions and New Criteria

| | | |
|--|---------------------------|---|
| Immunizations (f)(1) | By January 1, 2027 | Update to HL7 Version 2.5.1 IG for Immunization Messaging, Release 1.5 2018 Update and support new functionality to respond to incoming patient-level queries |
| Syndromic surveillance (f)(2) | By January 1, 2027 | Update to 2019 version of HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019 |
| Electronic lab reporting (f)(3) | By January 1, 2028 | Update to HL7 Version 2.5.1 LOI from EHR, Release 1 & LRI, Release 1, specifically the Public Health Profile within the IG and support new functionality for receipt of reportable lab orders and transmission of reportable lab results according to the IGs |
| Cancer registry reporting (f)(4) | By January 1, 2028 | Update to require the HL7 FHIR Central Cancer Registry Reporting Content IG 1.0.0 - STU1 and require support for Cancer pathology reporting according to the HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 |
| Electronic case reporting (f)(5) | By January 1, 2028 | Update to use the eICR profile of the HL7 FHIR eCR IG only |
| AU / AR (f)(6) | By January 1, 2027 | Update to HL7 CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - U.S. Realm |
| Health care surveys (f)(7) | By January 1, 2027 | Update HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 – US Realm |
| Birth reporting (f)(8) | New Criterion | HL7 FHIR Vital Records Birth and Fetal Death Reporting 1.1.0 – STU 1.1 |
| Prescription Drug Monitoring Program (f)(9) | New Criterion | Functional requirement to enable query of a PDMP, including bi-directional interstate exchange and to receive PDMP data in an interoperable manner |

Public Health Data Exchange- Revisions and New Criteria

Immunizations (f)(21)

Receive, validate, parse, and filter immunization information to advance bi-directional interoperability between health care and public health agencies

Standard: HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update

Syndromic Surveillance (f)(22)

Receive, validate, parse, and filter incoming syndromic surveillance information

Standard: HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019

Electronic lab reporting (f)(23)

Receive, validate, parse, and filter incoming reportable laboratory test results/values

Standard: HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 4 - US Realm (LRI), specifically the Public Health Profile within the Implementation Guide

Cancer Pathology Reporting (f)(24)

Receive, validate, parse, and filter incoming cancer pathology reports

HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1

Electronic Case Reporting (f)(25)

Receive, validate, parse, and filter of electronic case reports and reportability response

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) to the HL7 eCR FHIR IG

Birth Reporting (f)(28)

Receive, validate, parse, and filter incoming birth reports

HL7 FHIR Vital Records Birth and Fetal Death Reporting—1.1.0 - STU 1.1

Prescription Drug Monitoring Program (f)(29)

Receive, validate, parse, filter prescription data, support query and exchange electronic controlled substance medication prescription information through a FHIR-based API, Bulk FHIR, or SMTP-based edge protocol; or, optionally through TEFCA



HTI-2 Proposals Relevant to

Prescription Drug Monitoring Program (PDMP)

45 CFR 170.315(f)(9) and (f)(29)

Prescription Drug Monitoring Program (PDMP)

PROPOSAL

Two primary proposals relevant to PDMP

- New** “Prescription Drug Monitoring Program (PDMP) Databases – Query, receive, validate, parse, and filter. Functional requirement” at 170.315(f)(9)
 - Enable a user to query a PDMP, including bi-directional interstate exchange, to receive PDMP data in an interoperable manner, to establish access roles in accordance with applicable law, and to maintain records of access and auditable events

- New** Establish new certification criterion at 170.315(f)(29) “Prescription Drug Monitoring Program (PDMP) Data – Receive, validate, parse, filter prescription data, support query and exchange”
 - Enable a user to receive and validate electronic prescription information for controlled substance medications and support query and exchange of PDMP data (including patient access).

PDMP– Receive, validate, parse, filter prescription data, support query and exchange at 170.315(f)(9)

- Enable a user to query a PDMP, including bi-directional interstate exchange, to receive PDMP data in an interoperable manner, to establish access roles in accordance with applicable law, and to maintain records of access and auditable events as follows
- Query
 - Enable both passive and active bi-directional query of a PDMP, including an interstate exchange query upon the
 - Recording, change, or access of a medication order;
 - Creation and transmission of an electronic prescription for a controlled substance; and
 - Entry of controlled substance medication data into a medication list or reconciliation of a medication list including controlled substance medication data
 - Enable an active or user-initiated query of a PDMP including an interstate exchange query
 - Send an acknowledgement message in response to receipt of data after a query is performed

Workflows and functionalities for Health IT Modules certified to (f)(9) PDMP certification criterion

Initiate and enable both passive and active bi-directional query of a PDMP, including interstate exchange query



Module for f(9)

Receive, validate, parse, & filter electronic PDMP information received via Direct, FHIR API, SMTP-based edge protocol; or, optionally, through TEFCA

Parse and filter electronic PDMP information received and validated for any data element identified in at least one of the versions of the USCDI standard in § 170.213

Enable access controls, including for roles for delegate or surrogate under applicable law, and record and maintain an audit log

Workflows and functionalities for Health IT Modules certified to (f)(29) PDMP certification criterion

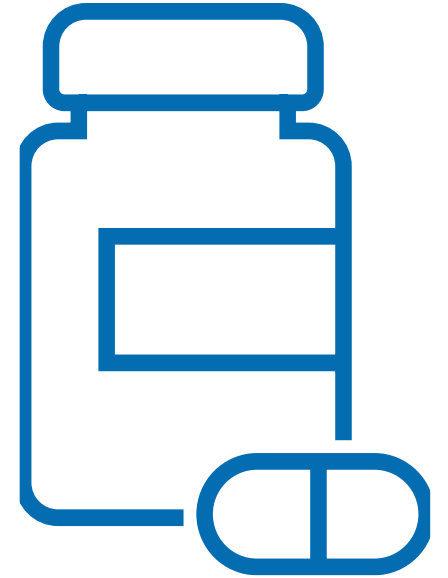
Receive, validate, parse, & filter electronic PDMP information received via Direct, FHIR API, SMTP-based edge protocol; or, optionally, through TEFCAs

Enable access controls, including for roles for delegate or surrogate under applicable law, and record and maintain an audit log

Enable patient-level queries from external systems of electronic controlled substance medication prescription information of the PDMP **including an interstate exchange query**

Respond to incoming patient-level queries from external systems

Enable patient access to view electronic controlled substance medication prescription information



Health IT for Public Health Module certified to (f)(29)

Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit <https://healthIT.gov/proposedrule> for additional information. More updates will be added over time.

- General Overview
- USCDI v4
- Electronic Prescription
- Information Blocking (Exceptions)
- Information Blocking (Definitions)
- Public Health Reporting
- TEFCA
- Modular API
- Patient, Provider, and Payer API
- Key Compliance Dates

JULY 2024
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability **PROPOSED RULE**

HTI-2 Proposed Rule Overview

Overview

Since the passage of the 21st Century Cures Act (Cures Act), the health IT and health care industry has made significant strides towards data interoperability throughout health care. The Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule builds on this foundation through new proposals that enable better and more equitable patient care through systemic improvements in the access, exchange, and use of data.

Key Proposals:

- A New Baseline Version of USCDI
- Minimum Standards Code Set Updates
- Bulk Data Enhancements
- Electronic Prior Authorization
- Information Blocking
- TEFCA™

New and Revised Standards and Certification Criteria Proposal

based on HLT's Fast Healthcare Interoperability Resources (FHIR) standard in the health care sector.

Exchange

ceptions under the information certification credentials, new criteria and API for public health reporting

Interoperable health IT standards and for existing data.

update the USCDI standard in the USCDI v4 and by expiration date of January 1, 2025 for purposes of the Program.

JULY 2024
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability **PROPOSED RULE**

HTI-2 Proposed Key Dates

HTI-2 Proposed Key Dates

Health IT developers with a Health IT Module certified to any revised certification criterion, as defined in 45 CFR 170.102, must update their certified Health IT Module and provide such updated health IT to their customers in accordance with the timelines defined for a specific criterion and/or standard included in § 170.315. Below are key dates for the certification criteria we propose to revise in HTI-2. Note, the new certification criteria proposed in HTI-2 have specified timelines for adoption in the ONC Health IT Certification Program (Program), but have been purposefully omitted from this fact sheet.

We propose that by January 1, 2026, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(d)(7) "privacy and security - health IT encryption"
- § 170.315(d)(9) "privacy and security - trusted connection"
- § 170.315(d)(12) "privacy and security - protect stored authentication credentials"

We propose that by January 1, 2027, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(f)(6) "public health - antimicrobial use and resistance reporting - transmission to public health agencies"
- § 170.315(f)(7) "public health - health care surveys - transmission to public health agencies"

We propose that by January 1, 2028, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

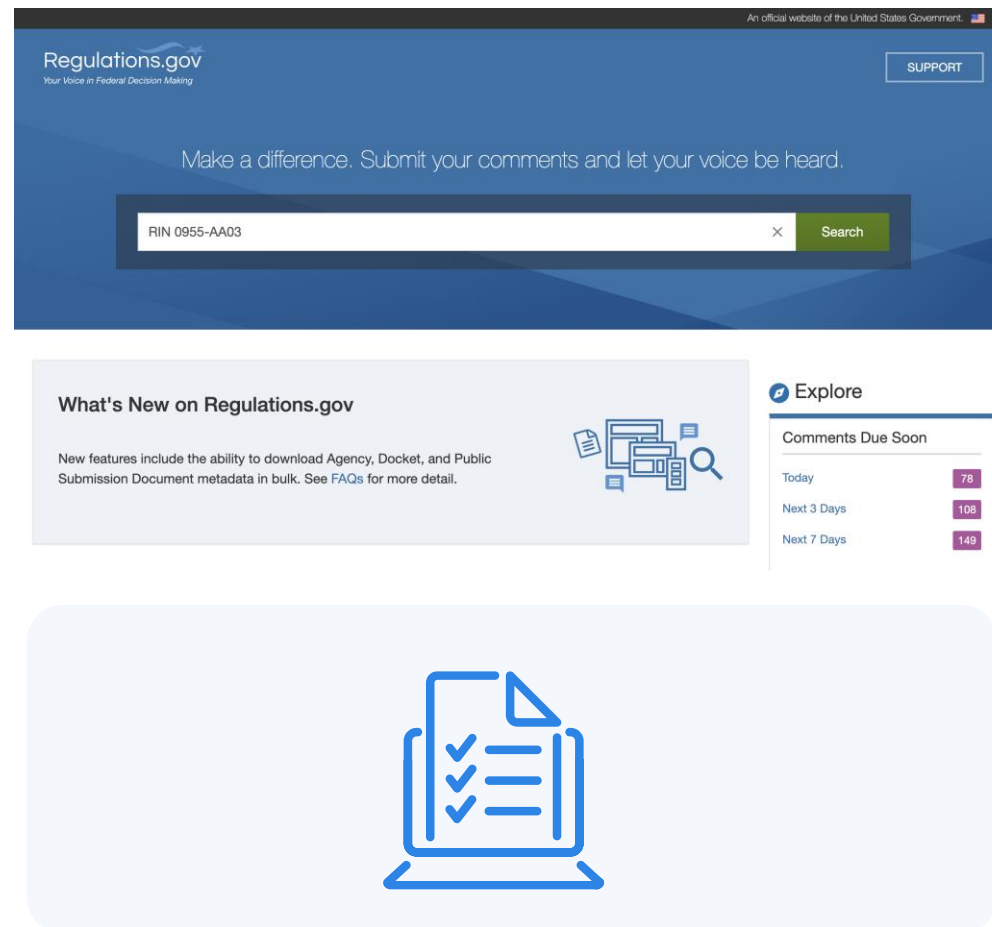
- § 170.315(a)(2) "computerized provider order entry - laboratory"
- § 170.315(a)(12) "family health history"
- § 170.315(b)(1) "transitions of care"
- § 170.315(b)(2) "clinical information reconciliation and incorporation"
- § 170.315(b)(3) "electronic prescribing"
- § 170.315(b)(4) "real-time prescription benefit"
- § 170.315(c)(4) "clinical quality measures - tier"
- § 170.315(d)(13) "privacy and security - multi-factor authentication"
- § 170.315(e)(1) "patient engagement - view, download, and transmit to 3rd party"
- § 170.315(f)(1) "public health - immunization registries"
- § 170.315(f)(2) "public health - syndromic surveillance - transmission to public health agencies"
- § 170.315(f)(3) "public health - reportable laboratory results"
- § 170.315(f)(4) "public health - cancer registry reporting"
- § 170.315(f)(5) "public health - transmission to public health agencies - electronic case reporting"
- § 170.315(f)(9) "design and performance - application access - all data request - functional requirements"
- § 170.315(g)(10) "design and performance - standardized API for patient and population services - data response"

HealthIT.gov

How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA06, through <http://www.regulations.gov>. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.



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