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

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

July 30, 2024

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AGENDA

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

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

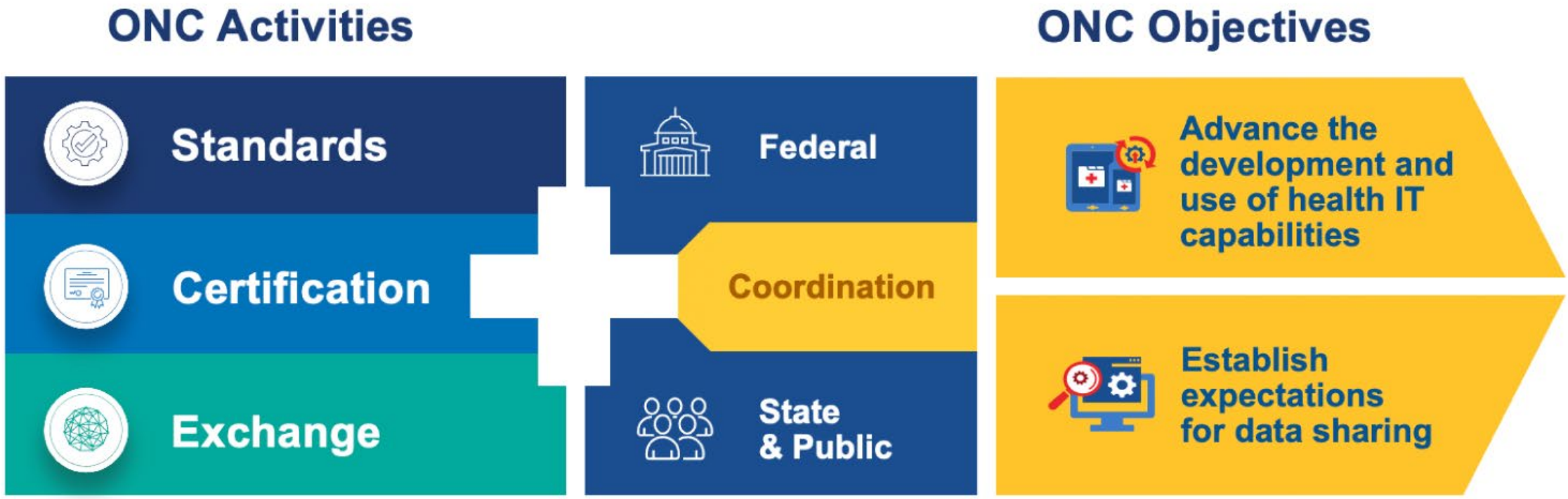
Achieving the Goals of the Biden-Harris Administration Executive Orders

- 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
Standards
Certification
Exchange
Federal
Coordination
State & Public
ONC Objectives
Advance the development and use of health IT capabilities
Establish expectations for data sharing

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

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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

Immunizations

45 CFR 170.315(f)(1) and (f)(21)

Immunization Information

PROPOSAL

- Two primary proposals relevant to immunization information
  - Revise “Transmission to immunization registries” certification criterion at 170.315(f)(1)
    - Revise transmission requirements via updated standards (HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, Published October 2018)
    - Update vocabulary standards (CVX and NDC)
    - Expire existing standards on January 1, 2027
    - Change name to “Immunization registries – Bi-directional exchange”
  - **New** Receive incoming patient-level immunization-specific query or request from external systems

New Establish new certification criterion at 170.315(f)(21) “Immunization information – Receive, validate, parse, filter, and –exchange - response” that would support:

- Enable a user to receive, validate, parse and filter electronic immunization information according to the updated HL7 2.5.1 IG
- Respond to incoming patient-level queries from external systems—including providing immunization information as structured data. Functional requirement.

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HTI-2 Proposals Relevant to

Syndromic Surveillance

45 CFR 170.315(f)(2) and (f)(22)

Syndromic Surveillance

PROPOSAL

- Two primary proposals relevant to syndromic surveillance
  - Revise “Transmission to public health agencies – syndromic surveillance” certification criterion at 170.315(f)(2)
    - Revise transmission requirements via updated standards (HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use)
    - Expire existing standards on January 1, 2027
    - Change name to “syndromic surveillance – transmission to public health agencies”

New Establish new certification criterion at 170.315(f)(22) “Syndromic Surveillance – Receive, validate, parse, and filter” that would support:

- Enable a user to receive, validate, parse and filter electronic syndrome-based public health surveillance information according to either the existing or newly identified HL7 2.5.1 Syndromic IG

HTI-2 Proposals Relevant to

Laboratory Orders and Results

45 CFR 170.315(f)(3), (f)(23), and (a)(2)

45 CFR 170.205(g)(1)-(3), 170.207

Laboratory Orders and Results

PROPOSAL

- Three primary proposals relevant to laboratory orders and results:
  - Update “electronic lab reporting” certification criterion at 170.315(f)(3), as “Reportable laboratory results – Transmission to public health agencies – and Laboratory Orders – Receive and validate,”
    - Revised transmission requirements via updated standards (HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Release 1 STU Release 4 – US Realm)

    New Receive and validate requirements via new standard (HL7 Version 2.5.1 Implementation Guide: Laboratory Orders Interface (LOI) from EHR, Release 1, STU Release 4 – US Realm)

  - Add functionality to “computerized provider order entry—laboratory” certification criterion at 170.315(a)(2) to:

    New Create and transmit laboratory orders using LOI IG

    New Receive laboratory results LRI IG

New Establish new certification criterion at 170.315(f)(23) “Reportable laboratory test values/results – Receive, validate, parse, and filter” that would support:

- Create, transmit, receive, and validate functionality using ELR and/or LRI IG

Add Functionality to "Computerized Provider Order Entry — Laboratory" Certification Criterion at 170.315(a)(2)

- Current criterion at (a)(2) states: Enable a user to record, change, and access laboratory orders
- New requirements for Health IT Modules certified to (a)(2) would enable a user to
  - Record, change, and access laboratory orders
  - Create and transmit laboratory orders electronically according to the LOI IG
  - Receive and validate laboratory results according to the LRI IG

HTI-2 Proposals Relevant to

Cancer Registry Reporting

45 CFR 170.315(f)(4) and (f)(24)

Cancer Registry Reporting

PROPOSAL

- Two primary proposals relevant to cancer registry reporting
  - Revise “Transmission to public health agencies – cancer registry reporting” certification criterion at § 170.315(f)(4)
    - Revise transmission requirements via updated standards:
      - HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm;

      OR

      - The cancer FHIR reporting bundle and accompanying profiles according to the HL7 FHIR Central Cancer Registry Reporting Content IG 1.0.0 - STU1 in § 170.205(i)(3), with the requirement that all data elements indicated as “mandatory” and “must support” in the IG must be supported
    - Expire existing standards on January 1, 2028

    New Include Cancer pathology reporting according to the HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1

    - Change name to “Cancer registry reporting – Transmission to public health agencies”

New Establish new certification criterion at § 170.315(f)(24) “Cancer pathology reporting – Receive, validate, parse, and filter” that would support:

- Enable a user to receive, validate, parse and filter cancer pathology information according to either the HL7 FHIR Cancer Pathology Data Sharing IG

HTI-2 Proposals Relevant to

Electronic Case Reporting

45 CFR 170.315(f)(5) and (f)(25)

Electronic Case Reporting

PROPOSAL

Two primary proposals relevant to electronic case reporting

- Revise “Transmission to public health agencies – electronic case reporting” certification criterion at § 170.315(f)(5)
  - Revise transmission requirements via updated standard (HL7 FHIR eCR IG)
  - Expire existing standards on January 1, 2028
  - Change name to “Electronic case reporting– transmission to public health agencies”

New

Establish new certification criterion at § 170.315(f)(25) “Electronic case reporting – Receive, validate, parse, filter electronic initial case reports and reportability response; and create and transmit reportability response ” that would support:

- Enable a user to receive, validate, parse and filter electronic case reports according to the identified HL7 eCR FHIR IG

HTI-2 Proposals Relevant to

Antimicrobial Use and Resistance Reporting

45 CFR 170.315(f)(6)

Antimicrobial Use and Resistance Reporting

PROPOSAL

- Update Health IT Modules certified to 170.315(f)(6) to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the following sections of the HL7 CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - U.S. Realm:
  - HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator);
  - Antimicrobial Resistance Option (ARO) Summary Report (Denominator); and,
  - Antimicrobial Use (AUP) Summary Report (Numerator and Denominator).

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HTI-2 Proposals Relevant to

Health Care Surveys

45 CFR 170.315(f)(7)

Health Care Surveys

PROPOSAL

- One primary proposals relevant to Health Care Surveys
  - Update Health IT Modules certified to 170.315(f)(7) to support the HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 – US Realm by January 1, 2027.

- Request for Comment on use of FHIR-based Health Care Surveys Content Implementation Guide
  - Should ONC consider modifying the certification criterion to require a Health IT Module to support creation and submission using at least the CDA or FHIR versions of the standard?

HTI-2 Proposals Relevant to

Birth Reporting

45 CFR 170.315(f)(8) and (f)(28)

Birth Reporting

PROPOSAL

Two primary proposals relevant to Birth reporting

New “Birth reporting—Transmission to public health agencies” at 170.315(f)(8)

- Create provider live birth report for electronic transmission in accordance with the HL7 FHIR Vital Records Birth and Fetal Death Reporting –1.1.0 –- STU 1.1

New Establish new certification criterion at 170.315(f)(28) “Birth reporting – Receive, validate, parse, and filter” accordance with the HL7 FHIR Vital Records Birth and Fetal Death Reporting –1.1.0 –- STU 1.1

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).

Standard API for Public Health Data Exchange

45 CFR 170.315(g)(20)
45 CFR 170.215(a), (b)(2), (d); 170.315(j)(1), (2), (7), (8), (23)

Standardized API for Public Health Data Exchange Proposal

PROPOSAL

We propose a standardized HL7 FHIR-based API for public health data exchange at § 170.315(g)(20) that would extend the capabilities included in the standardized API for patient and population services in § 170.315(g)(10). This new certification criterion would support ongoing and future development of public health FHIR IGs leveraging a core set of existing, modular, and extensible capabilities and standards.

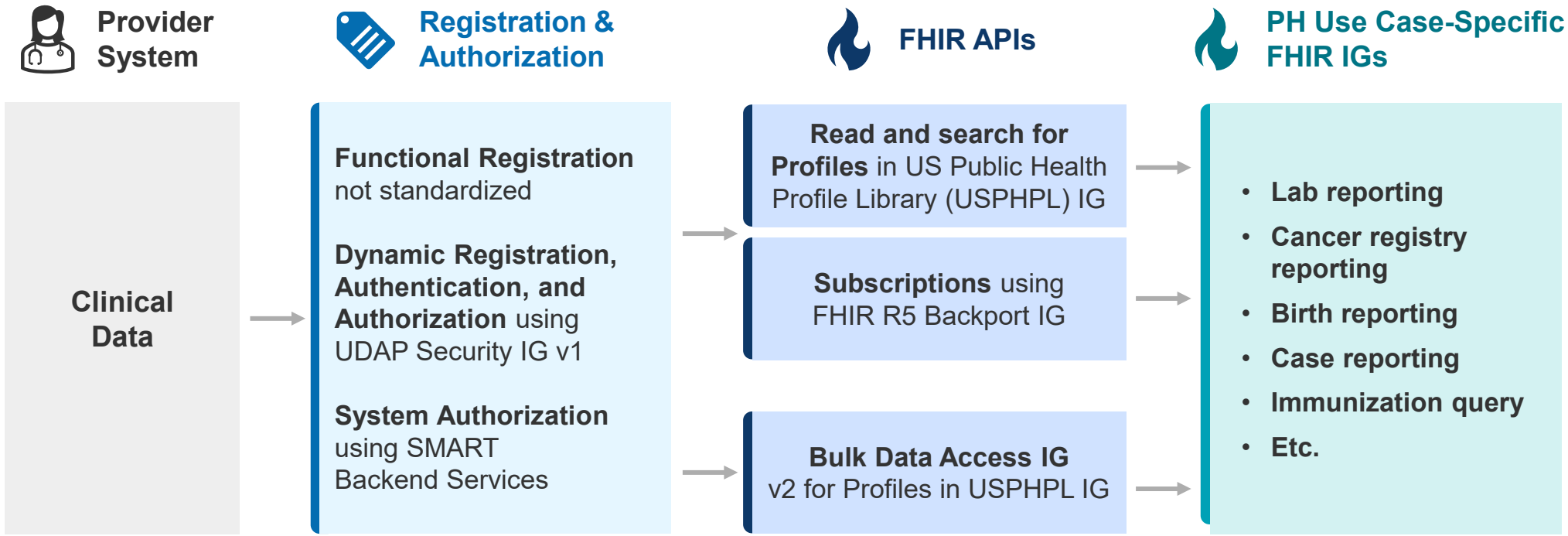
BENEFITS

- A necessary first step towards furthering a FHIR-based ecosystem that would support a wide array of public health data exchange use cases
- Better streamline and reduce reporting burden for healthcare organizations and developers, while expanding PHA's access to critical data for action
- Extend the capabilities included in the standardized API for patient and population services in § 170.315(g)(10) by requiring support for FHIR Resources Profiled in the United States Public Health Profiles Library Implementation Guide (USPHPL IG)
- Ensure that PHAs will have consistent access of discrete functionalities, defined capabilities, and standardized data from providers using certified health IT systems for a range of public health use cases
- Support ongoing and future development of public health FHIR IGs leveraging a core set of existing, modular, and extensible capabilities and standards

US Public Health Profile Library (USPHPL) Implementation Guide

- In proposing the USPHPL IG in § 170.215(b)(2), our intention is to leverage a public health-specific data set of common data elements necessary to support core public health exchange use cases.
  - The USPHPL IG contains reusable content profiles that represent common data PHAs and public health officials receive and use
  - It was created as a complement to the US Core IG—the USPHPL IG re-uses US Core profiles whenever possible, and only adds new profiles when there is a need for specific profiles for public health data exchange, and no corresponding profile in US Core IG
- We believe the USPHPL IG would enable the exchange of health data from healthcare organizations to PHAs with minimal implementation burden, due to its foundation in the US Core IG, and through the reuse of common profiles for public health data exchange purposes
- We intend to support updates to the USPHPL and align with USCDI+ Public Health

New Proposed Standardized API for Public Health Data Exchange (g)(20)

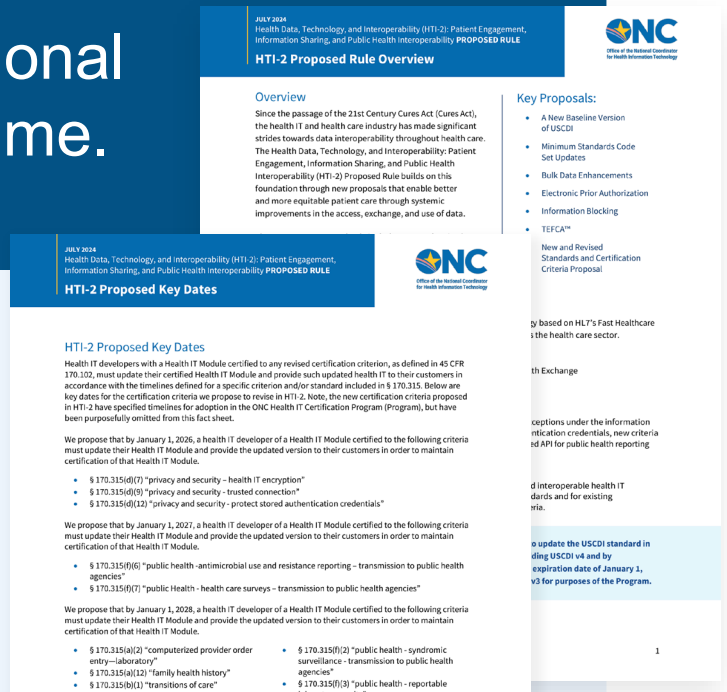


Resources Available on HealthIT.gov!

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

ONC Office of the National Coordinator for Health Information Technology

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

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

HTI-2 Proposed Key Dates

ONC Office of the National Coordinator for Health Information Technology

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 – filter"
- § 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(g)(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"

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