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

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

Disclaimers and Public Comment Guidance

- 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

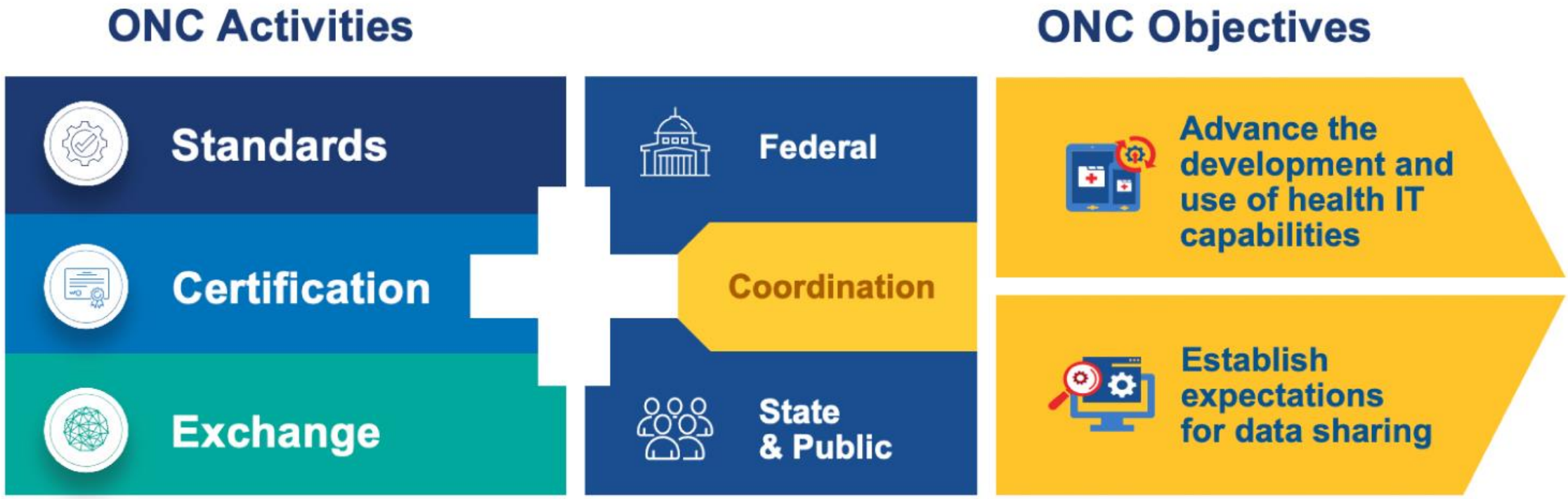
Achieving the Goals of the Biden-Harris Administration Executive Orders

- 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
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

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

Module for f(9)

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

- 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

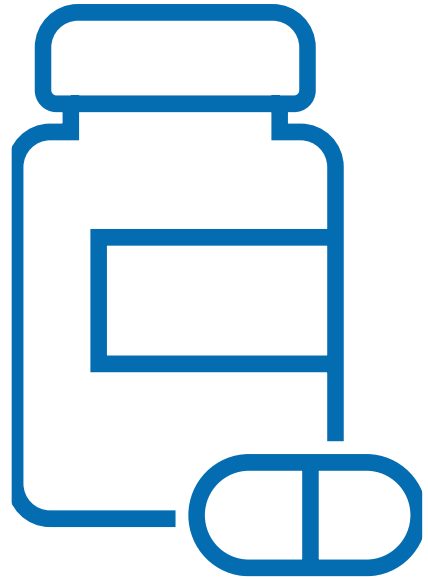
Receive, validate, parse, & filter electronic PDMP information received via Direct, FHIR API, SMTP-based edge protocol; or, optionally, through TEFCA

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



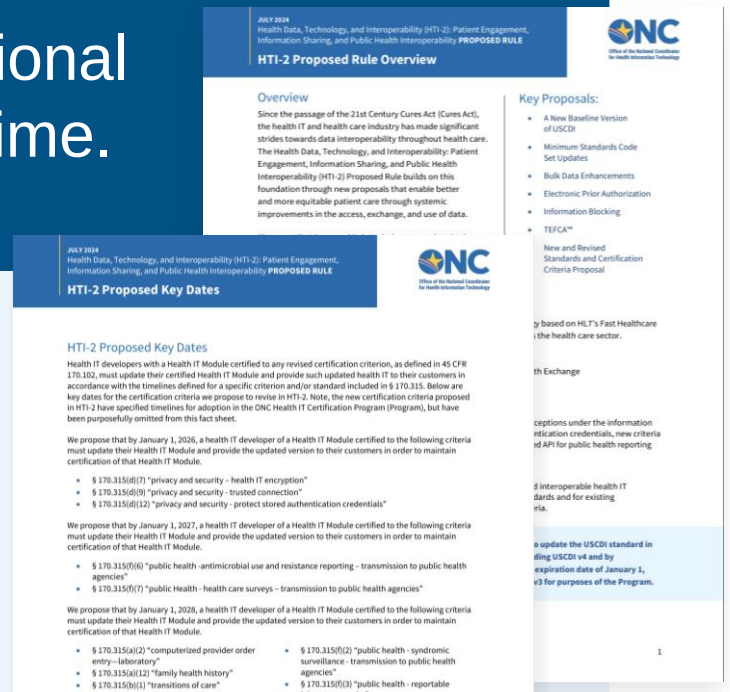
Health IT for Public Health Module certified to (f)(29)

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



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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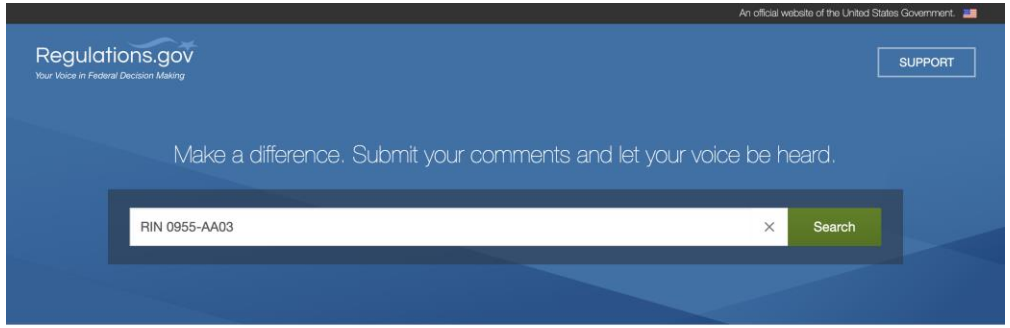

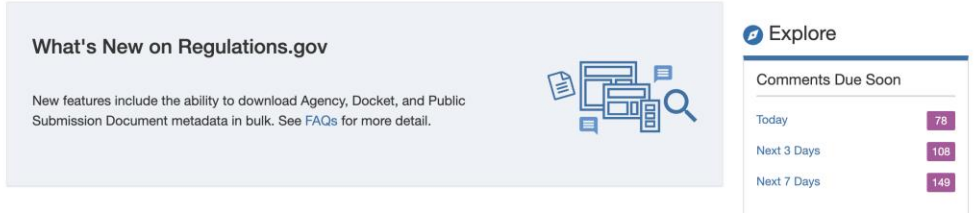

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