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

Public Health

ONC
Office of the National Coordinator for Health Information Technology

Overview

The Covid-19 pandemic affirmed the growing consensus that the Department of Health and Human Services (HHS) needs a new approach to nationwide public health infrastructure and data exchange. HHS is committed to creating a public health information framework that can rapidly and efficiently share data to produce actionable insights that inform local, state, and national public health situational awareness, decision-making, and interventions. CDC's Public Health Data Strategy (PHDS) outlines the data, technology, policy and administrative actions needed to exchange critical core data efficiently and securely across health care and public health. ONC's proposed rule supports and extends CDC and other HHS investments to advance data for public health action.

Key Proposals in HTI-2 Rule

ONC proposes a multi-pronged approach to public health updates and additions in HTI-2. ONC proposes updating existing certification criteria, adding new requirements for receipt, updating standards, and including a glidepath for transitioning to Fast Healthcare Interoperability Resources (FHIR®)-based exchange in the future. ONC proposes establishing minimum functional capabilities and exchange standards for health IT and health IT for public health to send and receive public health data. These proposals, outlined below, are expected to enhance interoperability across health care and public health and provide a long-term mechanism for alignment as data exchange matures over time.

Revised and new public health data transmission and exchange criteria

We propose revising the Program's current criteria related to public health in § 170.315(f) to add several new functional requirements and adopt newer versions of standards within current (f) criteria. We also propose to add two additional transmit criteria within § 170.315(f) for birth reporting and bi-directional exchange with a prescription drug monitoring program (PDMP).

The updates are the first comprehensive set of revisions to the (f) criteria since 2015, and support advancements in FHIR-based solutions and evolving standards related to public health interoperability. A summary of the (f) criteria updates are provided below:

Certification Criterion	Updates	Code-Set Updates	Transition Date
Immunizations (f)(1)	**Updated Standard**: Update to consolidated version of implementation guide and addendum: HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update **New Functionality**: Added functionality to respond to incoming patient-level queries according to adopted standard in (f)(1)	Yes	January 1, 2027
Syndromic (f)(2)	**Updated Standard**: Update to 2019 version of IG: HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019	No	January 1, 2027

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Certification Criterion	Updates	Code-Set Updates	Transition Date
Electronic Lab Reporting (f)(3)	**Updated Standard:** Update ELR IG and include: • HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 4 - US Realm • 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. **New Functionality:** New criterion for receipt of reportable laboratory orders and transmission of reportable laboratory results according to the LOI and LRI IGs	Yes	January 1, 2028
Computerized provider order entry (CPOE) – laboratory (a) (2)	**New Functionality:** Added create and transmit laboratory orders according to [LOI] Implementation Guide. Added receipt of laboratory results according to [LRI] Implementation Guide. **New standards**: • HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 4 - US Realm • 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.		January 1, 2028
Cancer Registry Reporting (f)(4)	**Updated Standard**: Updated to FHIR version of standard: HL7 FHIR Central Cancer Registry Reporting Content IG, 1.0.0 - STU 1 **New Functionality**: Addition of pathology lab reporting: HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1	Yes	January 1, 2028
Electronic Case Reporting (f)(5)	**Updated Standard:** Update to add expiration date in 2028 for 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) and require conformance to FHIR standard.	N/A	January 1, 2028
Antimicrobial Use and Resistance Reporting (f)(6)	**Updated Standard**: Update from 2013 IG to 2020 IG (Includes AUR, ARO, and AUP)	No	January 1, 2027
Health Care Surveys (f)(7)	**Updated Standard:** Update to most recent CCD-based IG **Request for Comment on FHIR IG**	No	January 1, 2027
Birth reporting (f)(8)	**New Criterion:** Transmission of a birth report according to the Birth and Fetal Death Reporting FHIR IG: Vital Records Birth and Fetal Death Reporting–1.1.0 - STU 1.1 (incorporated by reference in § 170.299). Vital Records Birth and Fetal Death Reporting–1.1.0 - STU 1.1	No	
Prescription Drug Monitoring (f)(9)	**New Criterion:** New functional criterion on bi-directional exchange of PDMP data	N/A	

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New criteria for public health information technology capabilities (health IT for public health)

In addition to revisions and additions to (f) criteria for transmission or bi-directional exchange of data with public health, we propose to adopt new certification criteria related to public health.

Due to health IT investments and varying programmatic requirements, there has been a divergence in minimum system capabilities and variable adoption and use of established national standards between certified health IT vendors and health IT for public health.

By establishing minimum functional capabilities and exchange standards for health IT to send and health IT for public health to receive public health data, we expect to enhance interoperability across health care and public health and provide a long-term mechanism for alignment as data exchange matures over time. Modernization efforts across health IT and health IT for public health will progress and upgrade on the same timeline, using the same standards across the ecosystem. Further, the capabilities we propose are intended to advance tools which can be used in a variety of ways across multiple programmatic and organizational use cases and processes.

A summary of the criteria, proposed in § 170.315(f)(21) through (29), is provided below:

Certification Criterion	Summary
Immunizations (f)(21)	**New Criterion:** New requirement to receive, validate, parse, and filter immunization information to advance bi-directional interoperability between health care and public health agencies **New Standard from (f)(1):** HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update **Request for Comment** on the functional requirement to respond to patient-level, immunization-specific queries from external systems
Syndromic (f)(22)	**New Criterion:** New requirement to receive, validate, parse, and filter incoming syndromic surveillance information **Updated Standard from (f)(2):** HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019
Electronic Lab Reporting (f)(23)	**New Criterion:** New requirement to receive, validate, parse, and filter incoming reportable laboratory test orders and results/values **Updated Standard from (f)(3):** 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)	**New Criterion:** New requirement to receive, validate, parse, and filter incoming cancer pathology reports **Updated Standard from (f)(4):** HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1
Electronic Case Reporting (f)(25)	**New Criterion:** New requirement to receive, validate, parse, and filter of electronic case reports and reportability response **Updated Standard from (f)(5):** 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)
Birth Reporting (f)(28)	**New Criterion:** New requirement to receive, validate, parse, and fileter incoming birth reports **New Standard from (f)(8):** Vital Records Birth and Fetal Death Reporting–1.1.0 - STU 1.1

Certification Criterion	Summary
Prescription Drug Monitoring (f)(29)	**New Criterion:** New functional requirement focused on the ability of health IT to receive and validate reported PDMP information, and to initiate and respond to queries from providers or other PDMP databases and hubs

New Standardized FHIR-based API for Public Health Reporting

ONC proposes to adopt a new criterion for a standardized FHIR-based API for public health data exchange in § 170.315(g)(20). This criterion would establish requirements for a standardized FHIR-based API for public health data exchange for data senders (e.g. EHR developers, HIT modules).

The new criterion would support broader use of FHIR-based exchange by public health by requiring HIT vendor support for a core set of capabilities that support public health data exchange use cases. This criterion will support ongoing and future development of public health FHIR Implementation Guides (IGs) by leveraging existing, generalizable, and extensible capabilities and standards.

The new criterion would include FHIR capabilities proposed in § 170.315(j), "Modular and foundational API capabilities." These criteria include FHIR capabilities such as Subscriptions, Bulk data export, and verifiable health records, and requirements for authorization and authentication, among others. The proposals in § 170.315(g)(20) also supports the capability for public health query of patient level data.