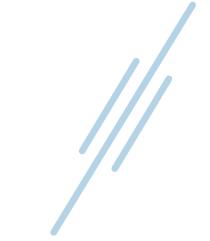# HTI-2 Proposed Rule Task Force 2024

Group 1: Public Health

Bryant Thomas Karras, Co-Chair

July 23, 2024

Call to Order/Roll Call

Peter Karras, Acting Designated Federal Officer, ONC

HTI-2 Proposed Rule Task Force 2024 Roster Group 1 Public Health

Name	Organization	Name	Organization
Bryant Thomas Karras* **(Co-Chair)**	Washington State Department of Health	Steven Hester*	Norton Healthcare
Shila Blend*	North Dakota Health Information Network	Erin Holt Coyne	Tennessee Department of Health
Hans Buitendijk*	Oracle Health	Jim Jirjis**	Centers for Disease Control and Prevention
Steven Eichner*	Texas Department of State Health Services	Mary Beth Kurilo	American Immunization Registry Association (AIRA)
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Kikelomo Oshunkentan*	Pegasystems
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Zeynep Sumer-King*	NewYork-Presbyterian
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)	Naresh Sundar Rajan*	CyncHealth
Joel Hartsell	Association of Public Health Laboratories	Thomas M. Wilkinson	U.S. Department of Homeland Security

* HITAC Member
** HITAC Federal Representative

Opening Remarks

Bryant Thomas Karras, Co-Chair

HTI-2 Proposed Rule Task Force 2024: Charge

Overarching Charge: The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

Specific Charge:
- Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.
- Recommendations are due prior to the end of the 60-day public comment period.

Agenda

11:00 AM   **Call to Order/Roll Call**
- Peter Karras, Acting Designated Federal Officer, ONC

11:05 AM   **Opening Remarks**
- Bryant Thomas Karras, Co-Chair

11:10 AM   **Health IT Modules Supporting Public Health Data Exchange Overview**
- Molly Prieto, ONC

11:25 AM   **Discussion**
- Bryant Thomas Karras, Co-Chair

11:35 AM   **Task Force Recommendation Worksheet**
- Bryant Thomas Karras, Co-Chair

12:20 PM   **Public Comment**
- Peter Karras, Acting Designated Federal Officer, ONC

12:25 PM   **Next Steps**
- Bryant Thomas Karras, Co-Chair

12:30 PM   **Adjourn**

Subgroup 1: Public Health

> The Public Health Subgroup will review and provide preliminary recommendations for Task Force consideration on the following HTI-2 proposed rule sections.

- ONC Health IT Certification Program Updates
  - New and Revised Standards and Certification Criteria
    - Health IT Modules Supporting Public Health Data Exchange Overview
    - Existing public health certification criteria in § 170.315(f)(1)-(f)(7) + (a)(2) for CPOE labs
    - New public health certification criteria in § 170.315(f)(8), (f)(9), and (f)(21)-(f)(29)
    - Continuation of new public health certification criteria in § 170.315(f)
    - New standardized API for public health data exchange in § 170.315(g)(20)
    - Update and revise recommendations

Health IT Modules Supporting Public Health Data Exchange Overview

Molly Prieto, ONC

Disclaimers and Public Comment Guidance

- The document that was posted to our website has been submitted to the Office of the Federal Register (OFR) for publication but has not yet been placed on public display or published in the <u>Federal Register</u>. The document may vary slightly from the published document if minor editorial changes have been made during the OFR review process. The document published in the <u>Federal Register</u> is the official HHS-approved document.

- 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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- This communication is produced and disseminated at U.S. taxpayer expense.

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

What Are We Proposing to Do?

‣ Advance health IT infrastructure nationwide;

‣ Minimize data silos so health IT users can access information from various settings;

‣ Emphasize technology solutions that are easier to adopt, particularly in settings with limited resources;

‣ Enhance interoperability across health care and public health;

‣ Advance equity;

‣ Support patients' access to lawful reproductive health care; and

‣ Strengthen support for actors honoring patients' individual privacy preferences

New and Revised

Public Health Data Exchange Certification Criteria

Public Health Data Exchange- Revisions and New Criteria

PROPOSAL

- ONC propose to update existing certification criteria for reporting public health data to include new and updated standards

- ONC also proposes to establish new certification criteria for reported public health data including the ability to receive, validate, parse and filter data according to standards

- ONC proposes a new, standards-based APIs for public health data exchange

BENEFITS

- 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.

- 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.

- 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.

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
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

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

Contact ONC

☎ 202-690-7151

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Discussion

Bryant Thomas Karras, Co-Chair

Task Force Recommendation Worksheet

Bryant Thomas Karras, Co-Chair

HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date	Agenda Items
7/23 (11 AM-12:30 PM ET)	• TF Subgroup 1 Meets • TF Topics: Health IT Modules Supporting Public Health Data Exchange Overview • Discussion/Early draft recommendations
7/30 (11 AM-12:30 PM ET)	• TF Subgroup 1 Meets • TF Topics: Existing public health certification criteria in §170.315(f)(1)-(f)(7) + (a)(2) for CPOE labs • Discussion/Early draft recommendations
8/6 (11 AM-12:30 PM ET)	• TF Subgroup 1 Meets • TF Topics: New public health certification criteria in §170.315(f)(8), (f)(9), and (f)(21)-(f)(29) • Update and revise recommendations
8/13 (11 AM-12:30 PM ET)	• TF Subgroup 1 Meets • TF Topics: Continuation of new public health certification criteria in §170.315(f) • Discussion/Early draft recommendations
8/20 (11 AM-12:30 PM ET)	• TF Subgroup 1 Meets: • TF Topics: New standardized API for public health data exchange in §170.315(g)(20) • Update and revise recommendations

HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date	Agenda Items
8/27 (11 AM-12:30 PM ET)	• ==TF Subgroup 1 Meets== • Update and revise recommendations
9/3 (11 AM-12:30 PM ET)	• Full TF Meets • Develop transmittal report/slides
9/4 (11 AM-12:30 PM ET)	• Full TF Meets • Develop transmittal report/slides
9/5 (11 AM-12:30 PM ET)	• Full TF Meets • Develop transmittal report/slides

Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

*(Once called upon, press "*6" to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

Written comments will not be read at this time,
but they will be delivered to members of the Task Force and made part of the public record

Next Steps

Bryant Thomas Karras, Co-Chair

Homework

- Review: Existing public health certification criteria in §170.315(f)(1)-(f)(7) + (a)(2) for CPOE labs:

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
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Upcoming Meetings

Task Force Meeting Date/Time
7/30 11 AM-12:30 PM
8/6   11 AM-12:30 PM
8/13 11 AM-12:30 PM
8/20 11 AM-12:30 PM
8/27 11 AM-12:30 PM
9/3   11 AM-12:30 PM (Full Task Force Meeting)
9/4   11 AM-12:30 PM (Full Task Force Meeting)
9/5   11 AM-12:30 PM (Full Task Force Meeting)

HITAC Meeting Date
8/15 TF provides updates to HITAC
9/12 TF delivers recommendations to HITAC

Adjourn