



# HTI-1 Proposed Rule Task Force 2023

## Group 3: ONC Health IT Certification Program Updates – Insights Condition, Standards Updates, and RFIs Meeting #11

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

May 18, 2023





# Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

# HTI-1 Proposed Rule Task Force 2023 – Group 3 Roster



<b>Name</b>	<b>Organization</b>
<b>Steven Eichner* (Co-Chair)</b>	Texas Department of State Health Services
<b>Steven Lane*(Co-Chair)</b>	Health Gorilla
<b>Hung Luu* (Group 3 Lead)</b>	Children's Health
Hans Buitendijk*	Oracle Health
Elaine Johanson**	FDA
Meg Marshall**	Department of Veterans Affairs (VA)
Clem McDonald*	National Library of Medicine
Naresh Sundar Rajan*	CyncHealth
Fillipe Southerland*	Yardi Systems, Inc.

\* HITAC Member

\*\* HITAC Federal Representative

# Agenda

- 10:30 AM**     **Call to Order/Roll Call**
  - Mike Berry, Designated Federal Officer, ONC
  
- 10:35 AM**     **HTI-1 Proposed Rule Task Force Charge**
  - Steven Eichner, Co-Chair
  - Steven Lane, Co-Chair
  
- 10:40 AM**     **Laboratory Data Interoperability Request for Information**
  - Carmela Couderc, ONC
  - Riki Merrick, Association of Public Health Laboratories
  - Craig Newman, Altarum
  - Eric Crugnale, Sonic Healthcare
  
- 11:50 AM**     **Public Comment**
  - Mike Berry, Designated Federal Officer, ONC
  
- 12:00 PM**     **Adjourn**



# HTI-1 Proposed Rule Task Force Charge

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

# HTI-1 Proposed Rule Task Force 2023

## Overarching Charge:

The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

## Specific Charge: Provide recommendations on ONC's proposals that would:

- Rename all certification criteria within the ONC Health IT Certification Program (Program) as “ONC Certification Criteria for Health IT” and discontinue year themed “Editions”
- Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3
- Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health information technology (health IT) developers under the Program
- Enhance information sharing under the information blocking regulations



# HTI-1 Proposed Rule Task Force 2023 (continued)

**Specific Charge:** Provide recommendations on ONC's proposals that would:

- Adopt new and revised standards and certification criteria, including:
  - Electronic case reporting certification criterion;
  - Clinical decision support (CDS) and decision support interventions (DSI) certification criteria;
  - Application programming interfaces (APIs) for patient and population services;
  - FHIR US Core Implementation Guide STU version 5.0.
  - HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm;
  - A new patient requested restrictions certification criterion; and
  - Requirements for health IT developers to update their previously certified health IT.
- Establish additional Assurances Condition and Maintenance of Certification requirements
- Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

**Recommendations are due to the HITAC by the end of the 60 day public comment period.**



## Group 3: ONC Health IT Certification Program Updates— Insights Condition, Standards Updates, and RFIs

- Insights Condition and Maintenance of Certification
- The United States Core Data for Interoperability Standard (USCDI) v3
- C-CDA Companion Guide Updates
- Standardized API for Patient and Population Services
- FHIR US Core Implementation Guide STU version 5.0.1
- **Requests for Information**





# Laboratory Data Interoperability Request for Information

Carmela Couderc, ONC

Riki Merrick, Association of Public Health Laboratories

Craig Newman, Altarum

Eric Crugnale, Sonic Healthcare

# Laboratory Data Interoperability Request for Information

<https://www.federalregister.gov/d/2023-07229/p-1351>

- In the 2015 Edition Proposed Rule, ONC proposed to adopt certification criteria specific to laboratory ordering that included HL7 version 2.5.1 Laboratory Order Interface (LOI) Release 2, Electronic Directory of Services (eDOS), and Laboratory Results Interface (LRI) Release 2 Implementation Guides (IGs). However, with consideration of public comments on the proposal, ONC did not adopt these IGs in the 2015 Edition Final Rule.
- Section 2213(b) of the Consolidated Appropriations Act, 2023 includes a provision directing ONC to conduct a study on the use of standards for electronic ordering and reporting of laboratory test results.
  - It specifies that ONC shall determine the extent to which clinical laboratories are using standards for electronic ordering and reporting of lab test results, assess trends in laboratory compliance with such standards and their effect on the interoperability of laboratory data with public health data systems, identify challenges related to collecting and reporting demographic and other data with respect to laboratory test results, identify challenges using or complying with standards and reporting laboratory test results with data elements identified in standards, and review other relevant areas determined appropriate by ONC.

→ ONC seeks comment on topics such as the use of health IT standards by clinical laboratories, use of such standards by labs and their effect on the interoperability of laboratory data with public health systems, including any challenges of the types identified above. We also seek comment on whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program.





# Discussion

Steven Eichner, Co-Chair

Steven Lane, Co-Chair



# Task Force Topics Worksheet

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

# 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](mailto: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*

# Upcoming Meetings

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	5/25	<ul style="list-style-type: none"> <li>RFI Pharmacy Interoperability Functionality, FHIR Subscriptions RFI; CDS Hooks RFI; FHIR Standard for Scheduling RFI; SMART Health Links RFI</li> </ul>
June	6/1	<ul style="list-style-type: none"> <li>Update and revise recommendations</li> </ul>
	6/6 (Full TF)	<ul style="list-style-type: none"> <li>Develop transmittal report/slides</li> </ul>
	6/7 (Full TF)	<ul style="list-style-type: none"> <li>Develop transmittal report/slides</li> </ul>
	6/8 (Full TF)	<ul style="list-style-type: none"> <li>Develop transmittal report/slides</li> </ul>
	6/13 (Full TF)	<ul style="list-style-type: none"> <li>Develop transmittal report/slides</li> </ul>
	<b>6/15 (HITAC)</b>	<ul style="list-style-type: none"> <li><b>Final Recommendation and Vote</b></li> </ul>

# HTI-1 Requests for Information Topics by Group

## Group 1 – Information Blocking (IB)

- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

## Group 3 – ONC Health IT Certification Program Updates– Insights Condition, Standards Updates, and RFIs

- **Laboratory Data Interoperability Request for Information**
- Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities
- FHIR Subscriptions Request for Information
- Clinical Decision Support Hooks Request for Information
- FHIR Standard for Scheduling Request for Information
- SMART Health Links Request for Information





**Adjourn**