



HTI-1 Proposed Rule Task Force 2023

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

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

April 27, 2023





Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

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

Name	Organization
Steven Eichner* (Co-Chair)	Texas Department of State Health Services
Steven Lane*(Co-Chair)	Health Gorilla
Hung Luu* (Group 3 Lead)	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 and Topics Worksheet

- Hung Luu, Group 3 Lead
- Steven Eichner, Co-Chair
- Steven Lane, Co-Chair

10:45 AM Insights Condition and Maintenance of Certification: Overview & Discussion

- Vaishali Patel, ONC

11:55 AM Public Comment

- Mike Berry, Designated Federal Officer, ONC

12:00 PM Adjourn



HTI-1 Proposed Rule Task Force Charge

Hung Luu, Group 3 Lead

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.




Task Force Topics Worksheet

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair



Insights Condition and Maintenance of Certification: Overview

Vaishali Patel, ONC



How were the measures developed?

- These first set of proposed measures focus on interoperability.
- ONC's contractor, The Urban Institute, developed a set of draft measures based on:
 - Research, including market research;
 - Input from stakeholders and health IT measurement experts; and
- Public feedback was obtained on the draft measures, including from the [2021 EHR Reporting Program Task Force](#) of the HITAC.
- The draft measures were revised based on HITAC and public feedback, along with additional research and feasibility testing, to create the current list of measures.

What are the measures?



	AREA	MEASURE	RELATED CRITERION/CRITERIA	
1	Individual Access to EHI	Individuals' Access to Electronic Health Information Supported by Certified API Technology	§§ 170.315(e)(1); 170.315(g)(10)	VDT to 3rd Party; Standardized API for Patient and Population Services
2	Clinical Care Information Exchange	C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism	§ 170.315(b)(2)	
	Clinical Care Information Exchange	C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation
4	Standards Adoption & Conformance	Applications Supported Through Certified Health IT	§ 170.315(g)(10)	Standardized API for Patient and Population Services
	Standards Adoption & Conformance	Use of FHIR in Apps Supported by Certified API Technology	§ 170.315(g)(10)	
	Standards Adoption & Conformance	Use of FHIR Bulk Data Access through Certified Health IT	§ 170.315(g)(10)	
	Standards Adoption & Conformance	Electronic Health Information Export (EHI) through Certified Health IT	§ 170.315(b)(10)	EHI export
2	Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information System Registries through Certified Health IT	§ 170.315(f)(1)	Transmission to Immunization Registries
	Public Health Information Exchange	Immunization History and Forecasts	§ 170.315(f)(1)	

Who will be reporting on these measures?

- Developers of certified health IT would be expected to report (as required by each measure) if they meet the following criteria:
 - They have at least 50 hospital users or 500 clinician users across their certified health IT products; and
 - Their product(s) are certified to the criterion/criteria associated with the measure; and
 - The developer has any users of the applicable criterion/criteria associated with the measure.
- Otherwise the health IT developer would report it does not meet the minimum reporting qualifications for that measure



What information will be submitted and how?

Data submitted should be aggregated or reported at the product level (across versions) in the format specified by the measure

- For example, if there are 3 versions of a product, the measure submitted would reflect data across all 3 versions rather than reporting on each separately.

Health IT developers shall submit documentation on the data sources and methodology used to generate submitted data

Optionally: Health IT developers may also submit descriptive or qualitative information to provide context as applicable

Submissions for the Insights Condition shall occur via web-based form and method, consistent with the requirement in § 3009A(c) of the PHSA, and shall be made publicly available via an ONC website



What is the reporting frequency and timeline?

Reporting of measures will be phased in over two years

- Year 1 will start with measures related to individual access, public health exchange and the applications supported through certified health IT measure
- Year 2 will follow with the rest of the measures

Submission Year 1

Includes the following 4 measures:

Individuals' access to electronic health information

Applications supported through certified health IT

Immunization administrations electronically submitted to immunization information system registries through certified health IT

Immunization history and forecasts

Submission Year 2

Adds the Following 5 Measures:

C-CDA documents obtained using certified health IT by exchange mechanism

C-CDA medications, allergies, and problems reconciliation and incorporation using certified health IT

Use of FHIR in apps supported by certified API technology

Use of FHIR bulk data access through certified health IT

Electronic health information export through certified health IT

What is the reporting frequency and timeline?



	Year 1												Year 2														
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec			
Reporting Periods				1 st Reporting Period						2 nd Reporting Period						3 rd Reporting Period						4 th Reporting Period →					
Generating Measures during "Assembly" Periods	<i>Collect Data</i>									1 st Assembly Period																	
																2 nd Assembly Period											
										<i>Assemble Data</i>												3 rd Assembly Period →					
Reporting window coincides with Condition & Maintenance of Certification																1 st									2 nd		

- Developers of certified health IT shall collect data for 6 months, and have an additional 6 months to assemble the measures from the data
- There is a one month reporting window
- Developers of certified health IT shall submit measures every six months
 - Reporting aligned with the "Attestations" Condition and Maintenance of Certification
 - Submission windows: April 1 – 30; October 1 – 31



Keys Areas to Review

1. Measures
 - a. Individual Access to EHI measure
 - b. Clinical Care Information Exchange measures
 - c. Standards Adoption & Conformance measures
 - d. Public Health Information Exchange measures

2. Reporting Requirements
 - a. Criteria to meet to report on each measure
 - b. Data to submit to report on each measure

3. Reporting Frequency and Timeline
 - a. First Reports Due
 - b. Frequency of Reporting



Discussion

Hung Luu, Group 3 Lead
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

*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	5/4	<ul style="list-style-type: none"> Insights Condition and Maintenance of Certification
	5/11	<ul style="list-style-type: none"> The United States Core Data for Interoperability Standard (USCDI) v3 C-CDA Companion Guide Updates
	5/17 (HITAC)	<ul style="list-style-type: none"> TF Update
	5/18	<ul style="list-style-type: none"> Standardized API for Patient and Population Services FHIR US Core Implementation Guide STU version 5.0.1
	5/25	<ul style="list-style-type: none"> Requests for Information
June	6/1	<ul style="list-style-type: none"> TBD
	6/6 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/7 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/8 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/13 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/15 (HITAC)	<ul style="list-style-type: none"> Final Recommendation and Vote



Adjourn