HTI-1 Proposed Rule Task Force 2023

Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria Meeting #12

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

May 19, 2023

Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

HTI-1 Proposed Rule Task Force 2023 – Group 2 Roster

Name	Organization
Steven Eichner* (Co-Chair/Group 2 Lead)	Texas Department of State Health Services
Steven Lane*(Co-Chair)	Health Gorilla
Medell Briggs-Malonson*	UCLA Health
Hans Buitendijk*	Oracle Health
Jim Jirjis*	HCA Healthcare
Anna McCollister*	Individual
Aaron Miri*	Baptist Health
Kikelomo Oshunkentan*	Pegasystems
Naresh Sundar Rajan*	CyncHealth
Fillipe Southerland*	Yardi Systems, Inc.
Sheryl Turney*	Elevance Health

* 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/Group 2 Lead
- Steven Lane, Co-Chair

10:40 AM **Electronic Case Reporting Certification Criteria**
- Jeff Smith, ONC
- Johnny Bender, ONC

11:10 AM **Steps Involved in Electronic Case Reporting**
- Jim Jirjis, HCA Healthcare (Task Force Member)
- John Loonsk, Johns Hopkins University

11:20 AM **Discussion**
- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

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/Group 2 Lead

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 2: ONC Health IT Certification Updates – New and Revised Certification Criteria

- Decision Support Interventions (DSI) and Predictive Models
- "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"
- Assurances Condition and Maintenance of Certification Requirements
- Requirement for Health IT Developers to Update their Previously Certified Health IT
- Electronic Case Reporting
- Patient Requested Restrictions Certification Criterion

Electronic Case Reporting Certification Criteria

Jeff Smith, ONC

Johnny Bender, ONC

Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing“ 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.

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.

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

Revised Criterion: § 170.315(f)(5) - Electronic Case Reporting

Electronic Case Reporting

Proposal

- ONC is proposing to require that Health IT Modules support eCR using consensus-based, industry-developed HL7® CDA and FHIR® standards
- Health IT Modules would need to support either:
  - HL7 CDA Implementation Guides for Electronic Initial Case Reports (eICR) and Reportability Response (RR) **or**
  - HL7 FHIR Implementation Guides to provide similar functionality and the Electronic Reporting **and**
  - Surveillance Distribution (eRSD) FHIR profile
- Developers of certified health IT may certify to revised standards and functionality 60-days after the effectiveness of a final rule; however, the must certify to revised criterion by January 1, 2025

Electronic Case Reporting

Benefits

- Facilitate transmission of electronic case reports to public health authorities
- Improve interoperability and implementation consistency
- Empower public health authorities to have an improved picture of where and when disease outbreaks occur
- Promote bi-directional exchange of health data between health care providers and public health authorities
- Promote the sharing of standardized knowledge artifacts related to electronic case reporting
- Enable the use of SVAP as newer standards emerge

FHIR-Based Approach Would Reference Specific Profiles within the eCR FHIR IG

- HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - US Realm 2.1.0 – STU 2 US
  - Electronic Initial Case Report (eICR) profile – Used to report a suspected case from healthcare to public health following the match of clinical data against a trigger code
  - Reportability Response (RR) profile – Used to communicate from public health to healthcare whether the initial case contained in the eICR is reportable and any related follow-up
  - Electronic Reporting and Surveillance Distribution (eRSD) profiles – Supports the distribution of reporting guidance and parameters, trigger code value sets, and more complex reporting rules
  - Data Element support would be required for
    - “Mandatory” and “must support” data elements across these profiles
    - eRSD Specification Library
    - eRSD Supplemental Library
    - Reportable Conditions Trigger Codes (RCTC) Value Set for Electronic Case Reporting
      - Regulatory baseline: RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022

CDA-Based Approach Would Reference Specific CDA IGs & the eRSD profile of the eCR FHIR IG

- HL7 CDA R2 Implementation Guides
  - 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 R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1 - US Realm
  - Support for data elements with minimum cardinality requirements equal to or greater than “1” and data elements with minimum cardinality requirements equal to or greater than "0" and a conformance verb of "SHOULD" or a "SHALL"

- HL7 FHIR IG, eRSD profiles – Supports the distribution of reporting guidance and parameters, trigger code value sets, and more complex reporting rules
  - “Mandatory” and “must support” data elements across these profiles would be required, in addition to those included as part of the eRSD Specification Library, the eRSD Supplemental Library, and Reportable Conditions Trigger Codes (RCTC) Value Set for Electronic Case Reporting
    - Regulatory baseline: RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022

Regulatory baseline: RCTC

- The RCTC value set currently includes
  - ICD-10 CM, SNOMED CT, LOINC, RxNorm, CVX, and CPT codes
  - Representing condition-specific diagnoses, resulted lab tests names, lab results, lab orders for conditions reportable upon suspicion, and medications for select conditions
- Given that the contents of the RCTC value set update frequently, we propose to recognize the RCTC value set as a minimum standard code set. This enables
  - ONC to reference a persistent version of the RCTC value set as a baseline for use in the Program
  - Developers of certified health IT to support newer or updated versions of RCTC value sets for their customers as soon as new releases are available
- Health IT Modules may voluntarily support an updated version (e.g., a subsequent release) of the RCTC value set
  - We anticipate that health IT developers would be incentivized by their customers to take advantage of this opportunity to voluntarily support updated versions of the RCTC value set because it will include new codes reflecting new or emerging infectious diseases.

Specifically, in § 170.315(f)(5)(ii) we propose that a Health IT Module enable a user to:

- Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4) received from the eRSD profiles as specified in the HL7 FHIR eCR IG in § 170.205(t)(1)
- Create a case report consistent with at least one of the following standards:
  - The eICR profile of the HL7 FHIR eCR IG in § 170.205(t)(1), or
  - The HL7 CDA eICR IG § 170.205(t)(2)
- Receive, consume, and process a case report response that is formatted to either the RR profile of the HL7 FHIR IG in § 170.205(t)(1) or the HL7 CDA RR IG in § 170.205(t)(3)
- Transmit a case report electronically to a system capable of receiving an electronic case report.

Proposal for Reporting and Requests for Comment

- ONC is proposing that the functional requirements for Health IT Modules certifying to (f)(5) remain agnostic as to which reporting platform the electronic case is transmitted
  - Rather, ONC proposes to require that the Health IT Module be capable of transmitting electronic case reports consistent with the reporting requirement(s) established by a PHA

- A Health IT Module certifying to (f)(5) may meet the reporting requirement by supporting electronic reporting to any system designated by the PHA and capable of receiving an electronic case report, such as:
  - State-based registry
  - Health Information Exchange
  - Other intermediary or proprietary platform (e.g., APHL AIMS)

- ONC seeks feedback on:
  - The option to use either CDA or FHIR or both IGs for certification;
  - Whether the eRSD profile is appropriate for Health IT Modules that use the CDA IG, as the CDA IG states;
  - Whether the eRSD profile is adequately defined to establish baseline functionality

Deadline for Transitioning to Revised (f)(5)

- Developers of certified health IT would have until December 31, 2024, to update and provide Health IT Modules certified to the proposed revised standards and functionality for (f)(5)
  - In proposed § 170.315(f)(5)(i) Enable a user to create an electronic case report for transmission meeting the requirements described in paragraphs § 170.315(f)(5)(i)(A) through (C) of this section for the time period up to and including December 31, 2024; or meet the requirements described in paragraph (f)(5)(ii) of this section

- Implications of this construct are
  - Developers who are ready to certify using CDA and/or FHIR approaches may do so as soon as a final rule is
  - Developers will have until January 1, 2025, to update and provide Modules certified to § 170.315(f)(5)(ii) to their clients

ONC | HealthIT ADVISORY COMMITTEE

Thank You

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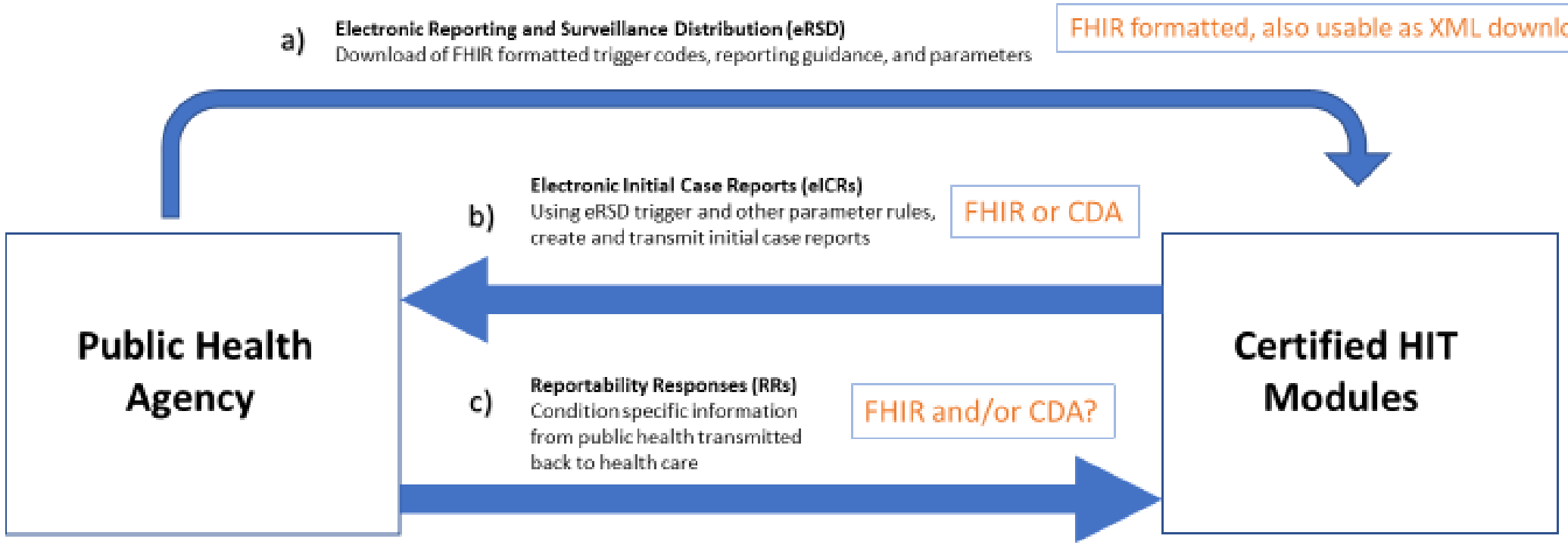
Steps Involved in Electronic Case Reporting

Jim Jirjis, HCA Healthcare (Task Force Member)

John Loonsk, Johns Hopkins University

Steps Involved in Electronic Case Reporting



- More than one eICR may be sent during an encounter as patient data accumulate.
- The initial eICR needs to be sent close to the start of the encounter to support state laws that require reporting on suspicion (for a limited set of conditions).
- Reporting should occur at the timing identified in the eRSD through a period after the encounter to include data like lab results that may not appear until the encounter has ended.

Discussion

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

Group 2: Discussion topics

Provide recommendations on ONC's proposals that would:

- Adopt revised electronic case reporting certification criterion

Task Force Topics Worksheet

Steven Eichner, Co-Chair/Group 2 Lead

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	5/24	• Patient Requested Restrictions Certification Criterion
	5/31	• TBD
June	6/6 (Full TF)	• Develop transmittal report/slides
	6/7 (Full TF)	• Develop transmittal report/slides
	6/8 (Full TF)	• Develop transmittal report/slides
	6/13 (Full TF)	• Develop transmittal report/slides
	6/15 (HITAC)	• **Final Recommendation and Vote**

Adjourn