HTI-1 Proposed Rule Task Force HITAC Update

Steven Lane, Co-Chair/Group 1 Lead

Steve Eichner, Co-Chair/Group 2 Lead

Hung Luu, Group 3 Lead

May 17, 2023

Agenda

- HTI-1 Proposed Rule Task Force Membership

- HTI-1 Proposed Rule Task Force Charge

- HTI-1 Proposed Rule Progress and Draft Recommendations
  - Group 1-Information Blocking (IB)
  - Group 2- ONC Health IT Certification Updates – New and Revised Certification Criteria
  - Group 3- ONC Health IT Certification Program Updates– Insights Condition, Standards Updates, and Requests for Information (RFIs)

- HTI-1 Proposed Rule Task Force Meeting Date and Timeline

HTI-1 Proposed Rule Task Force 2023 Roster

Name	Organization	Name	Organization
Steven Eichner* (Co-Chair)	Texas Department of State Health Services	**Steven Lane* (Co-Chair)**	Health Gorilla
Medell Briggs-Malonson*	UCLA Health	Anna McCollister*	Individual
Hans Buitendijk*	Oracle Health	Clem McDonald*	National Library of Medicine
Hannah Galvin*	Cambridge Health Alliance	Deven McGraw*	Invitae Corporation
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Aaron Miri*	Baptist Health
Adi Gundlapalli**	CDC	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Jim Jirjis*	HCA Healthcare	Kikelomo Oshunkentan*	Pegasystems
Elaine Johanson**	FDA	Naresh Sundar Rajan*	CyncHealth
Hung Luu*	Children's Health	Fillipe Southerland*	Yardi Systems, Inc.
Meg Marshall**	Department of Veterans Affairs (VA)	Sheryl Turney*	Elevance Health

* HITAC Member
** HITAC Federal Representative

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 1 : Information Blocking (IB)

Steven Lane

Steve Eichner

HTI-1 Proposed Rule Task Force 2023 – Group 1 Topics

Group 1: Information Blocking (IB)

- Information Blocking Defined Terms – Proposals

- IB Request for Information (RFI): Additional Exclusions for Offer Health IT

- IB Manner Exception - TEFCA Manner Proposal

- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

- IB Infeasibility Exception Proposals

  - Revise Existing Condition: Uncontrollable Events

  - New Condition: Third Party Seeking Modification Use

- New Condition: Manner Exception Exhausted

- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

*Highlighted = Topics discussed to date

Completed Group 1 Meeting Topics

Meeting Date	Area of Focus
May 2	IB Defined Terms-Proposals
May 9	IB Manner Exception - TEFCA Manner Proposal /IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
May 16	IB Infeasibility Exception Proposals

Upcoming Group 1 Meeting Topics

Meeting Date	Area of Focus	Invited External SME
May 23	• New Condition: Manner Exception Exhausted • IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access	Mohammad Jafari
May 30	Update and Revise Recommendations	N/A

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

Steve Eichner

Steven Lane

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

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

- <mark>Decision Support Interventions (DSI) and Predictive Models</mark>

- <mark>"The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"</mark>

- <mark>Assurances Condition and Maintenance of Certification Requirements</mark>

- <mark>Requirement for Health IT Developers to Update their Previously Certified Health IT</mark>

- Electronic Case Reporting

- Patient Requested Restrictions Certification Criterion

<mark>*Highlighted</mark> = Topics discussed to date

Completed Group 2 Meeting Topics

Meeting Date	Area of Focus	Invited External SME
April 26	Decision Support Interventions (DSI) and Predictive Models	N/A
May 3	Decision Support Interventions (DSI) and Predictive Models	Grace Cordovano, Enlightening Results
May 10	• The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions" • Requirement for Health IT Developers to Update their Previously Certified Health IT • Assurances Condition and Maintenance of Certification Requirements	N/A

Upcoming Group 2 Meeting Topics

Meeting Date	Area of Focus	Invited External SME
May 19	Electronic Case Reporting	John Loonsk, Johns Hopkins University
May 24	Patient Requested Restrictions Certification Criterion	Mohammad Jafari
May 31	Update and Revise Recommendations	N/A

Group 3 : ONC Health IT Certification Updates – New and Revised Certification Criteria

Hung Luu, Group 3 Lead

Steven Lane

Steve Eichner

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

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

- <mark>Insights Condition and Maintenance of Certification</mark>

- <mark>The United States Core Data for Interoperability Standard (USCDI) v3</mark>

- <mark>C-CDA Companion Guide Updates</mark>

- <mark>Standardized API for Patient and Population Services</mark>

- <mark>FHIR US Core Implementation Guide STU version 5.0.1</mark>

- Requests for Information

  - 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

*<mark>Highlighted</mark> = Topics discussed to date

Completed Group 3 Meeting Topics

Meeting Date	Area of Focus	Invited External SME
April 27	Insights Condition and Maintenance of Certification	N/A
May 4	(USCDI) v3, C-CDA, and FHIR US Core Revisions /Standardized API Updates	N/A
May 11	Insights Condition and Maintenance of Certification - EHRA Feedback and Discussion	Sasha TerMaat, Epic (EHRA)

Upcoming Group 3 Meeting Topics

Meeting Date

May 18

Area of Focus

Requests for Information
- Laboratory Data Interoperability Request for Information

Invited External SME

- Riki Merrick, Association of Public Health Laboratories
- Craig Newman, Altarum
- Erin Holt, Tennessee Department of Health
- Eric Crugnale, Sonic Healthcare USA

Upcoming Group 3 Meeting Topics

Meeting Date	Area of Focus	Invited External SME
May 25	Requests 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	• Shelly Spiro, Pharmacy HIT Collaborative • Margaret Welker, National Council for Prescription Drug Programs • Frank McKinney, Point-of-Care Partners • Brett Marquard, WaveOne Associates
June 1	Update and Revise Recommendations	N/A

Upcoming Full Task Force Meeting Topics

Meeting Date	Area of Focus
June 6	Update and finalize recommendations
June 7	Update and finalize recommendations
June 8	Update and finalize recommendations
June 13	Update and finalize recommendations
June 15	Recommendations delivered to the HITAC

Discussion