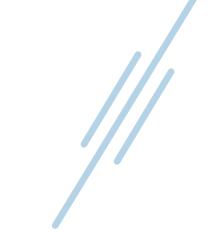# HTI-1 Proposed Rule Task Force 2023 Meeting #1

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

April 25, 2023

Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

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

Agenda

10:30 AM   **Call to Order/Roll Call**

- Mike Berry, Designated Federal Officer, ONC

10:35 AM   **Opening Remarks/Task Force Introductions**

- Steven Eichner, Co-Chair

- Steven Lane, Co-Chair

10:50 AM   **HTI-1 Proposed Rule Task Force Charge and Timelines**

- Steven Eichner, Co-Chair

- Steven Lane, Co-Chair

11:00 AM   **Decision Support Interventions (DSI) and Predictive Models**

- Kathryn Marchesini, ONC

- Jeff Smith, ONC

- Jordan Everson, ONC

11:50 AM   **Public Comment**

- Mike Berry, Designated Federal Officer, ONC

11:55 AM   **Task Force Work Planning**

- Steven Eichner, Co-Chair

- Steven Lane, Co-Chair

12:00 PM   **Adjourn**

Opening Remarks/Task Force Introductions

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

HTI-1 Proposed Rule Task Force 2023 Roster
(State name, organization, and title/role – please limit to 20 seconds)

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
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Jim Jirjis*	HCA Healthcare	Kikelomo Oshunkentan*	Pegasystems
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* HITAC Member
** HITAC Federal Representative

HTI-1 Proposed Rule Task Force Charge and Timelines

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.

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

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

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

Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria
- Decision Support Interventions (DSI) and Predictive Models
- Electronic Case Reporting
- "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
- Patient Requested Restrictions Certification Criterion

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

HTI-1 Proposed Rule Task Force 2023 – Group Assignment

Group 1		Group 2		Group 3	
Steven Lane* (Co-Chair/ Group 1 Lead)	Health Gorilla	**Steven Eichner* (Co-Chair/ Group 2 Lead)**	Texas Department of State Health Services	**Steven Lane* (Co-Chair)**	Health Gorilla
Steven Eichner* (Co-Chair)	Texas Department of State Health Services	**Steven Lane* (Co-Chair)**	Health Gorilla	**Steven Eichner* (Co-Chair)**	Texas Department of State Health Services
Hans Buitendijk*	Oracle Health	Hans Buitendijk*	Oracle Health	**Hung Luu* (Group 3 Lead)**	Children's Health
Hannah Galvin*	Cambridge Health Alliance	Medell Briggs-Malonson*	UCLA Health	Hans Buitendijk*	Oracle Health
Adi Gundlapalli**	CDC	Anna McCollister*	Individual	Jim Jirjis*	HCA Healthcare
Deven McGraw*	Invitae Corporation	Aaron Miri*	Baptist Health	Elaine Johanson**	FDA
Eliel Oliveira*	Dell Medical School, University of Texas at Austin	Kikelomo Oshunkentan*	Pegasystems	Meg Marshall**	Department of Veterans Affairs (VA)
Fillipe Southerland*	Yardi Systems, Inc.	Naresh Sundar Rajan*	CyncHealth	Clem McDonald*	National Library of Medicine
Sheryl Turney*	Elevance Health	Sheryl Turney*	Elevance Health	Naresh Sundar Rajan*	CyncHealth

* HITAC Member
** HITAC Federal Representative

HTI-1 Proposed Rule Task Force 2023 – Meeting Schedule

GROUP 1	GROUP 2	GROUP 3
Tuesdays 10:30 – Noon ET	Wednesdays, 10:30 – Noon ET	Thursdays, 10:30 – Noon ET

- All Task Force meetings are open to the public

- Registration and meeting materials can be found at: https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar

HTI-1 Proposed Rule Task Force 2023 – Draft Timeline

Proposed Meeting Date		Meeting #	Draft Agenda Items (need to prioritized topics)
Week 1	4/25	Meeting 1	• Full TF Kick-off Meeting • TF Topics: Decision Support Interventions (DSI) and Predictive Models (Group 2 topic)
	4/26	Meeting 2	• TF Group 2 Meets • TF Topics: Decision Support Interventions (DSI) and Predictive Models • Discussion/Early draft recommendations
	4/27	Meeting 3	• TF Group 3 Meets • TF Topics: Insights Condition and Maintenance of Certification • Discussion/Early draft recommendations
Week 2	5/2	Meeting 4	• TF Group 1 Meets • TF Topics: IB Defined Terms – Proposals • IB RFI: Additional Exclusions for Offer Health IT • Discussion/Early draft recommendations
	5/3	Meeting 5	• TF Group 2 Meets • TF Topics: Decision Support Interventions (DSI) and Predictive Models • Discussion/Early draft recommendations
	5/4	Meeting 6	• TF Group 3 Meets • TF Topics: Insights Condition and Maintenance of Certification • Discussion/Early draft recommendations

* Group 1: Information Blocking

   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 RFIs

HTI-1 Proposed Rule Task Force 2023 – Draft Timeline

Proposed Meeting Date	Meeting #	Draft Agenda Items (need to prioritized topics)

Week 3 5/9	Meeting 7	• TF Group 1 Meets
		• TF Topics:
		  ○ IB Manner Exception - TEFCA Manner Proposal
		  ○ IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
		• Discussion/Early draft recommendations

5/10	Meeting 8	• TF Group 2 Meets • TF Topics: "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 • Update and revise recommendations
5/11	Meeting 9	• TF Group 3 Meets • TF Topics: The United States Core Data for Interoperability Standard (USCDI) v3 • C-CDA Companion Guide Updates • Discussion/Early draft recommendations

* Group 1: Information Blocking
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 RFIs

HTI-1 Proposed Rule Task Force 2023 – Draft Timeline

Proposed Meeting Date		Meeting #	Draft Agenda Items (need to prioritized topics)
Week 4	5/16	Meeting 10	• ==TF Group 1 Meets== • TF Topics: IB Infeasibility Exception Proposals o Revise Existing Condition: Uncontrollable Events o New Condition: Third Party Seeking Modification Use • Update and revise recommendations
	5/18	Meeting 11	• ==TF Group 3 Meets== • TF Topics: Standardized API for Patient and Population Services • FHIR US Core Implementation Guide STU version 5.0.1 • Update and revise recommendations
	5/19	Meeting 12	• ==TF Group 2 Meets== • TF Topics: Electronic Case Reporting • Discussion/Early draft recommendations
Week 5	5/23	Meeting 13	• ==TF Group 1 Meets== • TF Topics: IB Infeasibility Exception Proposals • New Condition: Manner Exception Exhausted • Update and revise recommendations
	5/24	Meeting 14	• ==TF Group 2 Meets== • TF Topics: Patient Requested Restrictions Certification Criterion • Update and revise recommendations
	5/25	Meeting 15	• ==TF Group 3 Meets== • TF Topics: Requests for Information • Update and revise recommendations

* Group 1: Information Blocking
 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 RFIs

HTI-1 Proposed Rule Task Force 2023 – Draft Timeline

Proposed Meeting Date		Meeting #	Draft Agenda Items (need to prioritized topics)
Week 6	5/30	Meeting 16	• <mark>TF Group 1 Meets</mark> • TF Topics: IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access • Update and revise recommendations
	5/31	Meeting 17	• <mark>TF Group 2 Meets</mark> • TF Topics: TBD • Update and revise recommendations
	6/1	Meeting 18	• <mark>TF Group 3 Meets</mark> • TF Topics: TBD • Update and revise recommendations
Week 7	6/6	Meeting 19	• Full TF Meets • Develop transmittal report/slides
	6/7	Meeting 20	• Full TF Meets • Develop transmittal report/slides
	6/8	Meeting 21	• Full TF Meets • Develop transmittal report/slides
Week 8	6/13	Meeting 22	• Full TF Meets • Develop transmittal report/slides
	6/15		• TF delivers recommendations to HITAC

* Group 1: Information Blocking

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 RFIs

Decision Support Interventions (DSI) and Predictive Models

Kathryn Marchesini, ONC

Jeff Smith, ONC

Jordan Everson, ONC

Discussion

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

Task Force Work Planning

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

Upcoming Meetings

Month	Group#/Full TF	Task Force Meeting Dates	HITAC Meeting Date
April	**Full TF** Group 2 Group 3	4/25 4/26 4/27	
May	Group 1 Group 2 Group 3	5/2, 5/9, 5/16, 5/23, 5/30 5/3, 5/10, 5/19, 5/24, 5/31 5/4, 5/11, 5/18, 5/25	5/17 (TF Update)
June	Group 1 Group 2 Group 3 **Full TF**	 6/1 6/6, 6/7, 6/8, 6/13	6/15 (Final Recommendation and Vote)

Adjourn