



# HTI-2 Proposed Rule Task Force 2024 Meeting #1

Bryant Thomas Karras, Co-Chair

Rochelle Prosser, Co-Chair

Mark Sendak, Co-Chair

July 19, 2024





# Call to Order/Roll Call

Seth Pazinski, Designated Federal Officer, ONC



# Opening Remarks

- Bryant Thomas Karras, Co-Chair
- Rochelle Prosser, Co-Chair
- Mark Sendak, Co-Chair

# Agenda

**2:00 PM**      **Call to Order/Roll Call**

**2:10 PM**      **Opening Remarks**

**2:25 PM**      **HTI-2 Proposed Rule Task Force Charge and Work Plan**

**2:45 PM**      **Breakdown of HTI-2 Proposed Rule by Task Force Subgroups**

**3:20 PM**      **Public Comment**

**3:30 PM**      **Adjourn**

# HTI-2 Proposed Rule Task Force 2024 Roster

Name	Organization	Name	Organization
<b>Bryant Thomas Karras* (Co-Chair)</b>	Washington State Department of Health	<b>Rochelle Prosser* (Co-Chair)</b>	Orchid Healthcare Solutions
<b>Mark Sendak* (Co-Chair)</b>	Duke Institute for Health Innovation	Dominic H. Mack	Morehouse School of Medicine
Shila Blend*	North Dakota Health Information Network	Meg Marshall**	Department of Veterans Health Affairs
Hans Buitendijk*	Oracle Health	Anna McCollister*	Individual
Derek De Young*	Epic	Katrina Miller Parrish*	Patient.com
Steven Eichner*	Texas Department of State Health Services	Alex Mugge**	Centers for Medicare and Medicaid Services
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Shantanu Nundy	Accolade
Hannah Galvin*	Cambridge Health Alliance	Eliel Oliveira*	Harvard Medical School & Harvard Pilgrim Health Care Institute
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Kikelomo Oshunkentan*	Pegasystems
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)	Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Joel Hartsell	Association of Public Health Laboratories	Dan Riskin*	Verantos
Steven Hester*	Norton Healthcare	Fillipe Southerland*	Yardi Systems, Inc.
Erin Holt Coyne	Tennessee Department of Health	Zeynep Sumer-King*	NewYork-Presbyterian
Jim Jirjis**	Centers for Disease Control and Prevention	Naresh Sundar Rajan*	CyncHealth
Mary Beth Kurilo	American Immunization Registry Association (AIRA)	Sheryl Turney	Elevance Health
Hung S. Luu*	Children's Health	Thomas M. Wilkinson	U.S. Department of Homeland Security

\* HITAC Member

\*\* HITAC Federal Representative



# HTI-2 Proposed Rule Task Force 2024: Subgroup Group 1 Public Health Roster

Name	Organization
<b>Bryant Thomas Karras* (Co-Chair)</b>	Washington State Department of Health
Shila Blend*	North Dakota Health Information Network
Hans Buitendijk*	Oracle Health
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)
Joel Hartsell	Association of Public Health Laboratories
Erin Holt Coyne	Tennessee Department of Health
Mary Beth Kurilo	American Immunization Registry Association (AIRA)
Zeynep Sumer-King*	NewYork-Presbyterian
Sheryl Turney	Elevance Health
Thomas M. Wilkinson	U.S. Department of Homeland Security

\* HITAC Member

\*\* HITAC Federal Representative



# HTI-2 Proposed Rule Task Force 2024: Subgroup 2: Standards and Certification Roster

Name	Organization
<b>Mark Sendak* (Co-Chair)</b>	Duke Institute for Health Innovation
Hans Buitendijk*	Oracle Health
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Hung S. Luu*	Children's Health
Dominic H. Mack	Morehouse School of Medicine
Shantanu Nundy	Accolade

\* HITAC Member

\*\* HITAC Federal Representative



# HTI-2 Proposed Rule Task Force 2024: Subgroup 3 Information Blocking and TEFCA Roster

Name	Organization
<b>Rochelle Prosser* (Co-Chair)</b>	Orchid Healthcare Solutions
Shila Blend*	North Dakota Health Information Network
Hans Buitendijk*	Oracle Health
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Katrina Miller Parrish*	Patient.com
Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Zeynep Sumer-King*	NewYork-Presbyterian

\* HITAC Member

\*\* HITAC Federal Representative





# HTI-2 Proposed Rule Task Force Charge and Work Plan

Seth Pazinski, Designated Federal Officer, ONC



# HTI-2 Proposed Rule Task Force 2024: Charge

**Overarching Charge:** The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

## **Specific Charge:**

- Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.
- Recommendations are due prior to the end of the 60-day public comment period.



# Task Force Member Action Items

## 1. Subgroup Preferences

- Send your preference(s) for subgroups by **COB 7/19** to: Maggie Zeng ([lihua.zeng@hhs.gov](mailto:lihua.zeng@hhs.gov)) and Accel Solutions ([onc-hitac@accelsolutionsllc.com](mailto:onc-hitac@accelsolutionsllc.com))

## 2. Gmail Addresses

- Send your Gmail address to Accel ([onc-hitac@accelsolutionsllc.com](mailto:onc-hitac@accelsolutionsllc.com))
- We will be using Google Spreadsheets to work on recommendations collaboratively

## 3. ONC Presentation

- Please listen to the ONC presentation for [HTI-2 Proposed Rule Information Sessions](#)



# HTI-2 Proposed Rule Task Force 2024: Public Participation

- All Task Force meetings are open to the public
- Public comment is welcome in the chat throughout the meeting, and public comment time is included on all Task Force meeting agendas
- Calendar of HITAC meetings, meeting materials, and information on how the public can participate are available at: <https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar>



# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
<b>Week 1</b>	7/19 (2-3:30 PM)	Meeting 1	<ul style="list-style-type: none"><li>• Full TF Kickoff Meeting</li><li>• TF Topics: Breakdown of HTI-2 Proposed Rule by Task Force Subgroups</li></ul>

# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
<b>Week 2</b>	7/23 (11 AM-12:30 PM)	Meeting 2	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets</b></li> <li>• TF Topics: Health IT Modules Supporting Public Health Data Exchange Overview</li> <li>• Discussion/Early draft recommendations</li> </ul>
	7/24 (11 AM-12:30 PM)	Meeting 3	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics: Standardized API for Patient and Population Service including: <ul style="list-style-type: none"> <li>• USCDI Version 4, SMART App Launch 2.2, Bulk Data Enhancements 2.0, User-Access Brands and Endpoints, and Dynamic Client Registration Protocol</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>
	7/25 (11 AM-12:30 PM)	Meeting 4	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Information Blocking Enhancements <ul style="list-style-type: none"> <li>• Defined Terms – Health Care Provider, Health IT; Exceptions That Involve Practices Related to Actors’ Participation in TEFCA</li> <li>• Requestor Preferences Exception; “Interfere With” or “Interference” defined term</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>

**Subgroup 1: Public Health**

**Subgroup 2: Standards and Certification**

**Subgroup 3: Information Blocking and TEFCA**

# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
<b>Week 3</b>	7/30 (11 AM-12:30 PM)	Meeting 5	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets</b></li> <li>• TF Topics: Existing public health certification criteria in §170.315(f)(1)-(f)(7) + (a)(2) for CPOE labs</li> <li>• Discussion/Early draft recommendations</li> </ul>
	7/31 (11 AM-12:30 PM)	Meeting 6	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics: Modular API capabilities certification criteria in §170.315(j) + structure of §170.315(g)(10)</li> <li>• Discussion/Early draft recommendations</li> </ul>
	8/1 (11 AM-12:30 PM)	Meeting 7	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Information Blocking Enhancements               <ul style="list-style-type: none"> <li>• Protecting Care Access Exception</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>

**Subgroup 1: Public Health**

**Subgroup 2: Standards and Certification**

**Subgroup 3: Information Blocking and TEFCA**



# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
Week 4	8/6 (11 AM-12:30 PM)	Meeting 8	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets</b></li> <li>• TF Topics: New public health certification criteria in §170.315(f)(8), (f)(9), and (f)(21)-(f)(29)</li> <li>• Update and revise recommendations</li> </ul>
	8/7 (11 AM-12:30 PM)	Meeting 9	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics: Patient, Provider, and Payer APIs</li> <li>• Discussion/Early draft recommendations</li> </ul>
	8/8 (11 AM-12:30 PM)	Meeting 10	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Information Blocking Enhancements               <ul style="list-style-type: none"> <li>• Requestor Preferences Exception; “Interfere With” or “Interference” defined term</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>

**Subgroup 1: Public Health**

**Subgroup 2: Standards and Certification**

**Subgroup 3: Information Blocking and TEFCA**



# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
Week 5	8/13 (11 AM-12:30 PM)	Meeting 11	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets</b></li> <li>• TF Topics: Continuation of new public health certification criteria in §170.315(f)</li> <li>• Discussion/Early draft recommendations</li> </ul>
	8/13 (2-3:30 PM) <b>(8/15 Full HITAC Meeting)</b>	Meeting 12	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics:               <ul style="list-style-type: none"> <li>• Select Revised Certification Criteria and New Certification Criteria including:                   <ul style="list-style-type: none"> <li>• New Imaging Requirements for Health IT Modules, and Clinical Information Reconciliation and Incorporation</li> </ul> </li> </ul> </li> <li>• Security certification criteria revisions</li> <li>• Discussion/Early draft recommendations</li> </ul>
	8/14 (11 AM-12:30 PM)	Meeting 13	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Information Blocking Enhancements: Privacy Exception; Infeasibility Exception</li> <li>• Update and revise recommendations</li> </ul>

**Subgroup 1: Public Health**

**Subgroup 2: Standards and Certification**

**Subgroup 3: Information Blocking and TEFCA**

# HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date	Meeting #	Agenda Items
Week 6	8/20 (11 AM-12:30 PM)	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets:</b></li> <li>• TF Topics: New standardized API for public health data exchange in § 170.315(g)(20)</li> <li>• Update and revise recommendations</li> </ul>
	8/22 (10-11:30 AM)	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Trusted Exchange Framework and Common Agreement</li> <li>• Discussion/Early draft recommendations</li> </ul>
	8/22 (1-2:30 PM)	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics:</li> <li>• Select Revised Certification Criteria and New Certification Criteria including               <ul style="list-style-type: none"> <li>• Real-Time Prescription Benefit Criterion, Incorporation + Revised Electronic Prescribing Certification Criterion</li> </ul> </li> <li>• Security certification criteria revisions:               <ul style="list-style-type: none"> <li>• Multi-factor authentication certification criterion</li> <li>• End-user device encryption certification criterion + related standards</li> <li>• Certification criterion for encrypt authentication credentials</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>

Subgroup 1: Public Health

Subgroup 2: Standards and Certification

Subgroup 3: Information Blocking and TEFCA

# HTI-2 Proposed Rule Task Force 2024: Work Plan



Meeting Date		Meeting #	Agenda Items
<b>Week 7</b>	8/27 (11 AM-12:30 PM)	Meeting 17	<ul style="list-style-type: none"> <li>• TF Subgroup 1 Meets</li> <li>• Update and revise recommendations</li> </ul>
	8/28 (11 AM-12:30 PM)	Meeting 18	<ul style="list-style-type: none"> <li>• TF Subgroup 2 Meets</li> <li>• TF Topics: Conditions and Maintenance of Certification</li> <li>• Update and revise recommendations</li> </ul>
	8/29 (11 AM-12:30 PM)	Meeting 19	<ul style="list-style-type: none"> <li>• TF Subgroup 3 Meets</li> <li>• TF Topics: Administrative Updates</li> <li>• Update and revise recommendations</li> </ul>
<b>Week 8</b>	9/3 (11 AM-12:30 PM)	Meeting 20	<ul style="list-style-type: none"> <li>• Full TF Meets</li> <li>• Develop transmittal report/slides</li> </ul>
	9/4 (11 AM-12:30 PM)	Meeting 21	<ul style="list-style-type: none"> <li>• Full TF Meets</li> <li>• Develop transmittal report/slides</li> </ul>
	9/5 (11 AM-12:30 PM)	Meeting 22	<ul style="list-style-type: none"> <li>• Full TF Meets</li> <li>• Develop transmittal report/slides</li> </ul>

Subgroup 1: Public Health

Subgroup 2: Standards and Certification

Subgroup 3: Information Blocking and TEFCAs



## HTI-2 Proposed Rule Task Force 2024: Work Plan

Meeting Date		Meeting #	Agenda Items
<b>Week 9</b>	9/12		<ul style="list-style-type: none"><li>• TF delivers recommendations at full HITAC meeting</li></ul>



# Discussion



# Breakdown of HTI-2 Proposed Rule by Task Force Subgroups

Patient Engagement, Information Sharing, and Public Health  
Interoperability Proposed Rule

- Steven Posnack, Deputy National Coordinator for Health IT, ONC
- Sara McGhee, Policy Analyst, ONC

# HTI-2 Proposed Rule Overview

- The ONC HTI-2 Proposed Rule implements provisions of the 21st Century Cures Act and reflects ONC focused efforts to advance interoperability and improve information sharing among patients, health care providers, payers, and public health authorities.
- Key proposals include:
  - Two sets of new certification criteria, designed to enable health IT for public health as well as health IT for payers to be certified under the ONC Health IT Certification Program. Both sets of certification criteria focus heavily on standards-based application programming interfaces to improve end-to-end interoperability between data exchange partners (health care providers to public health and to payers, respectively).
  - Technology and standards updates that build on the HTI-1 Final Rule, ranging from the capability to exchange clinical images (e.g., X-rays) to the addition of multi-factor authentication support.
  - Requiring the adoption of United States Core Data for Interoperability (USCDI) version 4 by January 1, 2028.
  - Adjustments to certain “exceptions” to the information blocking regulations to cover additional practices that have recently been identified by the regulated community, including a new “Protecting Care Access” exception, which would cover practices an actor takes in certain circumstances to reduce its risk of legal exposure stemming from sharing information.
  - Establishing certain Trusted Exchange Framework and Common Agreement™ (TEFCA™) governance rules, which include requirements that implement section 4003 of the 21st Century Cures Act.





# HTI-2 Proposed Rule Task Force 2024: Task Force Structure

HITAC established one overarching Task Force with three subgroups to review and provide recommendations on the HTI-2 Proposed Rule within the 60-day public comment period.

## HTI-2 Proposed Rule Task Force 2024

Task Force Co-Chairs: Bryant Thomas Karras, Rochelle Prosser, Mark Sendak  
ONC Program Lead: Sara McGhee

### **Subgroup 1: Public Health**

Chair: Bryant Thomas Karras

ONC Program Leads: Rachel Abby, Molly Prieto

### **Subgroup 2: Standards and Certification**

Chair: Mark Sendak

ONC Program Lead: Sara McGhee

### **Subgroup 3: Information Blocking and TEFCA**

Chair: Rochelle Prosser

ONC Program Lead: Cassie Weaver





## Subgroup 1: Public Health HTI-2 Proposed Rule Provisions

- ONC Health IT Certification Program Updates
  - New and Revised Standards and Certification Criteria
    - Health IT Modules Supporting Public Health Data Exchange Overview
    - Existing public health certification criteria in §170.315(f)(1)-(f)(7) + (a)(2) for CPOE labs
    - New public health certification criteria in §170.315(f)(8), (f)(9), and (f)(21)-(f)(29)
    - Continuation of new public health certification criteria in §170.315(f)
    - New standardized API for public health data exchange in §170.315(g)(20)
    - Update and revise recommendations

## Subgroup 2: Standards and Certification

### HTI-2 Proposed Rule Provisions

- **ONC Health IT Certification Program Updates**
  - Standardized API for Patient and Population Service
    - The United States Core Data for Interoperability Version 4 (USCDI v4)
    - SMART App Launch 2.2
    - User-Access Brands and Endpoints
    - Bulk Data Enhancements
    - New Requirements to Support Dynamic Client Registration Protocol in the Program
  - Modular API capabilities certification criteria in §170.315(j) + Structure of §170.315(g)(10)
    - New Certification Criteria for Modular API Capabilities –
    - Revised structure for Patient and Population Services Criterion to Align with Modular API Capabilities
  - Patient, Provider, and Payer APIs
- Select Revised Certification Criteria and New Certification Criteria
  - New Imaging Requirements for Health IT Modules
  - Revised Clinical Information Reconciliation and Incorporation Criterion
  - New Real-Time Prescription Benefit Criterion
  - Revised Electronic Prescribing Certification Criterion
- Security Certification Criteria Revisions
  - Multi-factor Authentication Criterion
  - Revised End-User Device Encryption Criterion + related standards
  - Revised Criterion for Encrypt Authentication Credentials
- Conditions and Maintenance of Certification
  - Insights
  - Attestations



## Subgroup 3: Information Blocking and TEFCA

### HTI-2 Proposed Rule Provisions

- Information Blocking Enhancements
  - Defined Terms; Exceptions That Involve Practices Related to Actors' Participation in TEFCA
  - Protecting Care Access Exception
  - Requestor Preferences Exception, "Interfere With" or "Interference"
  - Privacy Exception; Infeasibility Exception
- Trusted Exchange Framework and Common Agreement
- Administrative Updates



# HTI-2 Proposed Rule Task Force Week 2 & Homework

Meeting Date		Meeting #	Agenda Items
<b>Week 2</b>	7/23 (11am-1pm)	Meeting 2	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 1 Meets</b></li> <li>• TF Topics: Health IT Modules Supporting Public Health Data Exchange Overview</li> <li>• Discussion/Early draft recommendations</li> </ul>
	7/24 (11am-1pm)	Meeting 3	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 2 Meets</b></li> <li>• TF Topics: Standardized API for Patient and Population Service including: <ul style="list-style-type: none"> <li>• USCDI Version 4, SMART App Launch 2.2, Bulk Data Enhancements 2.0, User-Access Brands and Endpoints, and Dynamic Client Registration Protocol</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>
	7/25 (11am-1pm)	Meeting 4	<ul style="list-style-type: none"> <li>• <b>TF Subgroup 3 Meets</b></li> <li>• TF Topics: Information Blocking Enhancements <ul style="list-style-type: none"> <li>• Defined Terms – Health Care Provider, Health IT; Exceptions That Involve Practices Related to Actors' Participation in TEFCA</li> </ul> </li> <li>• Discussion/Early draft recommendations</li> </ul>



# Discussion



# Public Comment

Seth Pazinski, Designated Federal Officer, ONC



# 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*



# Adjourn

- Bryant Thomas Karras, Co-Chair
- Rochelle Prosser, Co-Chair
- Mark Sendak, Co-Chair