



ONC HTI-2 Proposed Rule Task Force 2024

Group 3: Information Blocking and TEFCA

Rochelle Prosser, Co-Chair

July 25, 2024





Call to Order/Roll Call

Peter Karras, Acting Designated Federal Officer, ONC



Opening Remarks

Rochelle Prosser, Co-Chair

HTI-2 Proposed Rule Task Force 2024 Roster

Group 3 Information Blocking and TEFCA

Name	Organization	Name	Organization
Rochelle Prosser* (Co-Chair)	Orchid Healthcare Solutions	Katrina Miller Parrish*	Patient.com
Shila Blend*	North Dakota Health Information Network	Kris Mork	Guidehouse
Hans Buitendijk*	Oracle Health	Eliel Oliveira*	Harvard Medical School & Harvard Pilgrim Health Care Institute
Derek De Young*	Epic	Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Steven Eichner*	Texas Department of State Health Services	Zeynep Sumer-King*	NewYork-Presbyterian
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Naresh Sundar Rajan*	CyncHealth
Hannah Galvin*	Cambridge Health Alliance	Sheryl Turney	Elevance Health
Dominic H. Mack	Morehouse School of Medicine	Rachel Walker	University of Massachusetts Amherst
Anna McCollister*	Individual		

* HITAC Member

** HITAC Federal Representative

Agenda

- 11:00 AM Call to Order/Roll Call**
 - Peter Karras, Acting Designated Federal Officer, ONC
- 11:05 AM Opening Remarks**
 - Rochelle Prosser, Co-Chair
- 11:10 AM Information Blocking Enhancements**
 - Rachel Nelson, ONC & Cassie Weaver, ONC
- 11:25 AM Discussion**
 - Rochelle Prosser, Co-Chair
- 11:35 AM Task Force Recommendation Worksheet**
 - Rochelle Prosser, Co-Chair
- 12:20 PM Public Comment**
 - Peter Karras, Acting Designated Federal Officer, ONC
- 12:25 PM. Next Steps**
 - Rochelle Prosser, Co-Chair
- 12:30 PM Adjourn**



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.



Subgroup 3: Information Blocking and TEFCA

The Information Blocking and TEFCA Subgroup will review and provide preliminary recommendations for Task Force consideration on the following HTI-2 proposed rule sections.

- Administrative Updates
- **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



Information Blocking Enhancements

Rachel Nelson, ONC & Cassie Weaver, ONC



Information Blocking — Definitions

“Business Day”

PROPOSAL

Codify that for purposes of information blocking regulations “business day” (or “days”) means Monday through Friday except for public holidays specified in U.S. code or declared a (federal) holiday by federal statute or executive order.

BENEFITS

- Would give actors and other interested parties certainty as to which days count as “business days” for purposes of information blocking regulations.
- Same days would count as “business days” under information blocking as (we propose) would count for purposes of ONC Health IT Certification Program regulations.

“Health Care Provider”

PROPOSAL

ONC proposes to update wording of the information blocking regulations’ “health care provider” definition to include explicit reference to the definitions of “laboratory” and “pharmacist” in the same section of the statute as the currently cited definition of “health care provider.”

BENEFITS

- Enhanced certainty for laboratories, pharmacists, and other interested parties of precisely what “laboratory” and “pharmacist” mean within the definition of “health care provider” for purposes of the information blocking regulations.

“Health Information Technology” or “Health IT”

PROPOSAL

Codify that for purposes of the information blocking regulations “health information technology” (and its short form “health IT”) have the same meaning as they do in ONC’s authorizing statute.

BENEFITS

- Enhanced certainty for actors and other interested parties as to what the term “health IT” means within the information blocking regulations.

“Interfere With” or “Interference”

PROPOSAL

ONC proposes to add a section (§ 171.104) to the information blocking regulations that would codify that certain practices (acts and omissions) constitute “interference” for purposes of the information blocking definition.

BENEFITS

- The proposal would give actors (and those who seek to interact with them to access, exchange, or use EHI) confidence that certain practices of the following general kinds will be “interference” for purposes of the information blocking definition:
 - Actions taken by an actor to impose delays on other persons’ access, exchange, or use of EHI;
 - Non-standard implementation of health IT and other acts to limit interoperability of EHI or the manner in which EHI is accessed, exchanged, or used by other persons;
 - Improper inducements or discriminatory contract provisions; and
 - Omissions (failures to act) when action is necessary to enable or facilitate appropriate information sharing, such as where access, exchange, or use of an individual’s EHI is required by law or where it is permitted by law and not subject to restrictions requested by the individual (to which an actor has agreed).
- Proposal would not set a fixed universe of practices that could constitute “interference,” leaving important room for case-by-case assessment across current variations in health IT and future innovations.

Certain Practices Constituting “Interference”

ONC proposes to codify:

- *A non-exhaustive list of practices constituting an interference*
- Without regard to whether an exception applies or the practice is required by law
- *Not* a list of information blocking practices
- Other practices will also constitute interferences



Certain Practices Constituting “Interference”

(a) The following constitute practices that are likely to interfere with the access, exchange, or use of electronic health information (EHI) for purposes of § 171.103:

(1) **Delay on new access.** Delaying patient access to new EHI, such as diagnostic testing results, so clinicians or other actor representatives can review the EHI.

(2) **Portal access.** Delaying patient access to EHI in a portal when the actor has the EHI and the actor’s system has the technical capability to support automated access, exchange, or use of the EHI via the portal.

(3) **API access.** Delaying the access, exchange, or use of EHI to or by a third-party app designated and authorized by the patient, when there is a deployed application programming interface (API) able to support the access, exchange, or use of the EHI.

(4) **Non-standard implementation.** Implementing health information technology in ways that are likely to restrict access, exchange, or use of EHI with respect to exporting electronic health information, including, but not limited to, exports for transitioning between health IT systems.

(5) **Contract provisions.** Negotiating or enforcing a contract provision that restricts or limits otherwise lawful access, exchange, or use of EHI.

(6) **Non-compete provisions in agreements.** Negotiating or enforcing a clause in any agreement that:

- (i) prevents or restricts an employee (other than the actor’s employees), a contractor, or a contractor’s employee
- (ii) who accesses, exchanges, or uses the EHI in the actor’s health IT
- (iii) from accessing, exchanging, or using EHI in other health IT in order to design, develop, or upgrade such other health IT.

Certain Practices Constituting “Interference”

(7) ***Manner or content requested.*** Improperly encouraging or inducing requestors to limit the scope, manner, or timing of EHI requested for access, exchange, or use.

(8) ***Medical images.*** Requiring that the access, exchange, or use of any medical images (including, but not limited to, photograph, x-rays, and imaging scans) occur by exchanging physical copies or copies on physical media (such as thumb drive or DVD) when the actor and the requestor possess the technical capability to access, exchange, or use the images through fully electronic means.

(9) ***Omissions.*** The following omissions:

- (i) Not exchanging EHI under circumstances in which such exchange is lawful;
- (ii) Not making EHI available for lawful use;

(iii) Not complying with another valid law enforceable against the actor that requires access, exchange or use of EHI;

(iv) A Certified API Developer (as defined in 45 CFR 170.404) failing to publish API discovery details as required by the maintenance of certification requirement in 45 CFR 170.404(b)(2);

(v) An API Information Source (as defined in 45 CFR 170.404) failing to disclose to the Certified API Developer the information necessary for the Certified API Developer to publish the API discovery details required by 45 CFR 170.404(b)(2).

(b) The acts and omissions that will constitute practices that are likely to interfere with the access, exchange, or use of electronic health information (EHI) for purposes of § 171.103 include acts and omissions beyond those listed in paragraph (a) of this section.

TEFCA Practices for Purposes of Part 171

PROPOSAL

We propose that it would not be interference for TEFCA Qualified Health Information Networks™ (QHINs™), Participants, or Subparticipants to comply with required provisions of the Common Agreement and the incorporated TEFCA Terms of Participation and TEFCA Standard Operating Procedures, respectively.

BENEFITS

- This proposal is intended to provide assurances to information blocking actors who choose to participate in TEFCA that complying with the requirements of TEFCA as a QHIN, Participant, or Subparticipant would not be considered an interference for purposes of the information blocking definition.
- We believe providing such assurance supports the policy goals of the Cures Act and information blocking by advancing interoperability and expanding secure access, exchange, and use of electronic health information.



Task Force Recommendation Worksheet

Rochelle Prosser, Co-Chair



Discussion

Rochelle Prosser, 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*



Next Steps

Rochelle Prosser, Co-Chair

Upcoming Meetings

Task Force Meeting Date/Time

8/1 11 AM - 12:30 PM

8/8 11 AM -12:30 PM

8/14 11 AM -12:30 PM

8/22 10 -11:30 AM

8/29 11 AM -12:30 PM

9/3 11 AM -12:30 PM (Full Task Force Meeting)

9/4 11 AM -12:30 PM (Full Task Force Meeting)

9/5 11 AM -12:30 PM (Full Task Force Meeting)

HITAC Meeting Date

8/15 TF provides updates to HITAC

9/12 TF delivers recommendations to HITAC





Adjourn