



ASTP/ONC HTI-2 Proposed Rule Task Force 2024

Group 3: Information Blocking and TEFCA

Rochelle Prosser, Co-Chair

August 1, 2024





Call to Order/Roll Call

Peter Karras, Acting Designated Federal Officer, ASTP/ONC

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	Anna McCollister*	Individual
Shila Blend*	North Dakota Health Information Network	Katrina Miller Parrish*	Patient.com
Hans Buitendijk*	Oracle Health	Kris Mork	Guidehouse
Sooner Davenport	Southern Plains Tribal Health Board	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 (Rae) Walker	University of Massachusetts Amherst

* HITAC Member

** HITAC Federal Representative



Opening Remarks

Rochelle Prosser, Co-Chair

Agenda

- 11:00 AM** **Call to Order/Roll Call**
 - Peter Karras, Acting Designated Federal Officer, ASTP/ONC

- 11:05 AM** **Opening Remarks**
 - Rochelle Prosser, Co-Chair

- 11:10 AM** **Information Blocking Enhancements**
 - Rachel Nelson, ASTP/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, ASTP/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, ASTP/ONC



Information Blocking — New Exception: Protecting Care Access

New Protecting Care Access Exception

PROPOSAL

Under its specified conditions, the exception would apply to practices likely to interfere with EHI access, exchange, or use an actor believes in good faith could create or increase a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought:

- under law in effect at the time the actor engages in the practice;
- against patients, health care providers, or those who help make providing or receiving care possible;
- for the mere fact that
 - a person sought, obtained, provided, or facilitated reproductive care that was lawful under the conditions in which it was provided; or
 - (where the patient protection condition applies) a patient has health conditions or history for which reproductive health care is often sought, obtained, or medically indicated.

BENEFITS

- Offers actors certainty that practices satisfying the exception will not be considered “information blocking”
- Assures patients that the information blocking regulations support actors limiting EHI sharing in response to risks that arise over time, while also continuing to support patients’ own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that fosters better patient care.
- Supports continued advances in digitization, interoperability, and public confidence in the nationwide health information technology infrastructure.

New Protecting Care Access Exception

OVERVIEW

An actor's practice implemented to reduce the risk of potential exposure to legal action would not be information blocking when the actor's practice satisfies at least 2 conditions:

Threshold



Patient Protection

< OR >

Care Access

- **Threshold Condition Requirements:**
 - 1) Belief (an actor holds in good faith)
 - 2) Tailoring (of practice)
 - 3) Implementation (of practice) based on actor's
 - organizational policy – or –
 - case-by-case determination

- **Patient Protection Condition** – applicable to practices actor believes could reduce the patient's risk of potential exposure to legal action based on mere fact reproductive health care sought/received or a health history or condition for which reproductive health care often sought, received, or medically indicated

- **Care Access Condition** – applicable to practices actor believes could reduce potential exposure to legal action of health care providers or other persons who provide care or are otherwise involved in facilitating reproductive health care that is lawful under circumstances provided



Protecting Care Access Exception (Proposed New § 171.206)

An actor's practice that is implemented to reduce potential exposure to legal action will not be considered information blocking when the practice satisfies the condition in paragraph (a) of this section and also satisfies the requirements of at least one of the conditions in paragraphs (b) or (c) of this section.

(a) *Threshold Condition*

(b) *Patient Protection Condition*

(c) *Care Access Condition*

(d) *Presumption.* For purposes of determining whether an actor's practice meets the *patient protection* or *care access* condition's requirements, care is presumed to be lawful unless actor has actual knowledge that the care was not lawful under the circumstances in which it was furnished.

(e) *Definition of legal action.* As used in this section, legal action means any one or more of the following—

- (1) a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care;
- (2) a civil or criminal action brought in a court to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care; or
- (3) an administrative action or proceeding against any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Protecting Care Access Exception — *Threshold Condition*

§ 171.206 (a) To satisfy this condition, a practice must meet each of the following requirements:

(1) *Belief.* The practice is undertaken based on the actor's good faith belief that: (i) Persons seeking, obtaining, providing, or facilitating reproductive health care are at risk of being potentially exposed to legal action that could arise as a consequence of particular access, exchange, or use of specific electronic health information; and (ii) Specific practices likely to interfere with such access, exchange, or use of such electronic health information could reduce that risk.

(2) *Tailoring.* The practice is no broader than necessary to reduce the risk of potential exposure to legal action that the actor in good faith believes could arise from the particular access, exchange, or use of the specific electronic health information.

(3) *Implementation.* The practice is implemented either consistent with an organizational policy that meets paragraph (a)(3)(i) of this section or pursuant to a case-by-case determination that meets paragraph (a)(3)(ii) of this section.

(i) An organizational policy must: (A) Be in writing;

(B) Be based on relevant clinical, technical, and other appropriate expertise;

(C) Identify the connection or relationship between the interference with particular access, exchange, or use of specific electronic health information and the risk of potential exposure to legal action that the actor believes the interference could reduce;

(D) Be implemented in a consistent and non-discriminatory manner; and

(E) Conform to the requirements in paragraphs (a)(1) and (a)(2) of this section and to the requirements of at least one of the conditions in paragraphs (b) or (c) of this section that are applicable to the prohibition of the access, exchange, or use of the electronic health information.

(ii) A case-by-case determination is made by the actor: (A) In the absence of an organizational policy applicable to the particular situation;

(B) Based on facts and circumstances known or reasonably believed by the actor at the time of the determination;

(C) That conforms to the conditions in paragraphs (a)(1) and (2) of this section; and

(D) Is documented either before or contemporaneous to engaging in any practice based on the determination.

Documentation of the determination must identify the connection or relationship between the interference with particular access, exchange, or use of specific electronic health information and the risk of potential exposure to legal action.

Protecting Care Access Exception — *Patient Protection Condition*

§ 171.206 (b) When implemented for the purpose of reducing the patient’s risk of potential exposure to legal action, the practice must:

(1) Affect only the access, exchange, or use of specific electronic health information the actor in good faith believes could expose the patient to legal action because the electronic health information shows, or would carry a substantial risk of supporting a reasonable inference, that the patient:

- (i) Obtained reproductive health care;
- (ii) Inquired about or expressed an interest in seeking reproductive health care; or
- (iii) Has any health condition or history for which reproductive health care is often sought, obtained, or medically indicated.

(2) Be subject to nullification by an explicit request or directive from the patient that the access, exchange, or use of the specific electronic health information occur despite the risk(s) to the patient that the actor has identified.

(3) For purposes of paragraph (b)(1) and (b)(2) of this section, “patient” means the natural person who is the subject of the EHI or another natural person referenced in, or identifiable from, the EHI as a person who has sought or obtained reproductive health care.

Protecting Care Access Exception — *Care Access Condition*

§ 171.206 (c) When implemented for the purpose of reducing the risk of potential exposure to legal action for one or more licensed health care professionals, other health care providers, or other persons involved in providing or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, the practice must affect only access, exchange, or use of specific electronic health information that the actor believes could expose a care provider(s) and facilitator(s) to legal action because the information shows, or would carry a substantial risk of supporting a reasonable inference, that they provide or facilitate, or have provided or have facilitated, reproductive health care.



Protecting Care Access Exception — Additional Details

- Defining “**reproductive health care**” for purposes of this exception: We propose to adopt in § 171.102, by cross-reference to 45 CFR 160.103, the same definition of “reproductive health care” as is now used for purposes of the HIPAA regulations in 45 CFR parts 160 and 164. (This proposal is discussed in section IV.B.3.a of the HTI-2 NPRM.)

Health care provider is defined in § 171.102 along with other information blocking terms

- We propose in HTI-2 to clarify the wording of the “health care provider” definition, but not to change its scope. (Please see discussion in section IV.A.1 of the HTI-2 NPRM.)

Person is defined in § 171.102 by cross-reference to the definition of “person” in 45 CFR 160.103

- Effective June 25, 2024, the § 160.103 definition clarifies what “natural person” means in this context

45 CFR 171.102 as currently codified can be found here: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-A/section-171.102>

45 CFR 160.103 as currently codified can be found here: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160/subpart-A/section-160.103>



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

8/8 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