



# HITAC HTI-2 Proposed Rule Task Force 2024

## Group 3: Information Blocking and TEFCA

Rochelle Prosser, Co-Chair

August 8, 2024





# Call to Order/Roll Call

Seth Pazinski, Designated Federal Officer, ASTP

# HTI-2 Proposed Rule Task Force 2024 Roster

## Group 3 Information Blocking and TEFCA



Name	Organization	Name	Organization
<b>Rochelle Prosser*</b> <b>(Co-Chair)</b>	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**
  - Seth Pazinski, Designated Federal Officer, ASTP
  
- 11:05 AM**      **Opening Remarks**
  - Rochelle Prosser, Co-Chair
  
- 11:10 AM**      **Information Blocking Enhancements**
  - Dan Healy, ASTP
  
- 11:25 AM**      **Discussion**
  - Rochelle Prosser, Co-Chair
  
- 11:35 AM**      **Task Force Recommendation Worksheet**
  - Rochelle Prosser, Co-Chair
  
- 12:20 PM**      **Public Comment**
  - Seth Pazinski, Designated Federal Officer, ASTP
  
- 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

Dan Healy, ASTP



# Infeasibility Exception Updates

# Infeasibility Exception — Overview

(a)(1) *Uncontrollable events...* (no change proposed)

**(a)(2) *Segmentation*** (update proposed)

**(a)(3) *Third party seeking modification use*** (update proposed)

(a)(4) *Manner exception exhausted* (no change proposed)

(a)(5) *Infeasible under the circumstances* (no change proposed)

**(b) *Responding to requests*** (must be met in complement to at least 1 condition from paragraph (a)) (update proposed)

# Infeasibility Exception — Segmentation Condition Update

## PROPOSAL

Expand application of the condition to circumstances where an actor cannot segment from other EHI the EHI that they cannot share or have chosen to withhold. Specifically, the *expansion* would make the condition applicable where the actor has chosen to withhold EHI consistent with:

- Privacy sub-exceptions applicable to denials of individual access on unreviewable grounds (§ 171.202(d)) or health IT developer of certified health IT not covered by HIPAA (§ 171.202(c))
- Proposed new Protecting Care Access Exception (§ 171.206)

## BENEFITS

- Would accommodate more circumstances where another exception would apply to an actor choosing to withhold some EHI under an applicable exception but the actor cannot unambiguously segment that EHI from other requested EHI (that applicable law allows the actor to share).

# Infeasibility Exception — *Third Party Modification Use Condition Update*

## PROPOSAL

Revise the condition so it would not apply when third party modification use is sought:

- By any HIPAA covered entity or business associate from an actor that is their business associate
- By any health care provider who is not a HIPAA covered entity from an actor whose activities **would** make the actor a business associate of that same health care provider if that health care provider were a HIPAA covered entity.

## BENEFITS

- Recognizes the need of covered entities and their business associates to regularly modify EHI held by other business associates of the same covered entity.
- Recognizes that health care providers who are not HIPAA covered entities often have similar relationships with actors who provide services that would make the actor a business associate if the health care provider were a HIPAA covered entity, and that these providers may need or want a third party to modify EHI held by such actors on their behalf.

# Infeasibility Exception — *Responding to Requests Condition Update*

## PROPOSAL

Revise the *responding to requests* condition (§ 171.204(b)) to offer actors a more flexible response timeframe where the reason(s) for infeasibility are consistent with the *manner exception exhausted* (§ 171.204(a)(4)) or *infeasible under the circumstances* (§ 171.204(a)(5)) conditions.

Retain existing ten-business-day response timeframe where reason(s) for infeasibility are consistent with the *uncontrollable events* (§ 171.204(a)(1)), *segmentation* (§ 171.204(a)(2)), or *third party seeking modification use* (§ 171.204(a)(3)) conditions

## BENEFITS

- Would allow responding actors who initiate good-faith collaborative engagement with the requestor within ten business days of the actor receiving the request a flexible timeframe within which to discuss the potential infeasibility of the request as received and potentially feasible alternative ways to achieve information sharing.
- For requestors, in addition to more flexible time for discussions with the actor, would continue to provide for a response indicating reason(s) for infeasibility within 10 days of the actor's determination of infeasibility.
- For both actors and requestors, revised wording would offer enhanced clarity as to when the 10 business day timeframe for responding to requests infeasible for reasons consistent with the uncontrollable events (§ 171.204(a)(1)), segmentation (§ 171.204(a)(2)), or third party seeking modification use (§ 171.204(a)(3)) starts.

# Infeasibility Exception — *Responding to Requests* Alternative Proposal

## PROPOSAL

HTI-2 includes an alternative proposal would establish maximum timeframe(s) within which good faith discussions and negotiations must, in order for the *responding to requests* (§ 171.204(b)) to be met, reach a plan to proceed or an actor's determination that a particular requested access, exchange, or use of EHI is not feasible.

Under the alternative proposal, the maximum amount of time would be:

- 3, 5, 10, 20, or 30 business days after the date the actor receives any initial request; or
- one of those timeframes for any request that does not implicate the HIPAA Privacy Rule's individual right of access (45 CFR 164.524) and the maximum timeframe allowed under 45 CFR 164.524 for those requests that do also implicate it.

## BENEFITS

- A maximum timeframe requirement would create additional clarity for actors and predictability for requestors.



# Request for Comment: TEFCA Manner Exception

# Request for Comment – TEFCA Manner Exception

We finalized a new TEFCA Manner Exception in the HTI-1 Final Rule. We stated that the new TEFCA Manner Exception (§ 171.403) provides that an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use EHI to be providing such access, exchange, or use to only via TEFCA will not be considered information blocking when it follows certain conditions (89 FR 1388).

## We request comment on:

- **Fees & Licensing:** Whether there are drawbacks to applying the Fees and Licensing Exceptions, and if we should continue to apply them to the TEFCA Manner Exception as currently required in § 171.403(d).
- **API FHIR Limitation:** Should the limitation be expanded to include exchange based on versions of the FHIR standards that are more advanced than those adopted in 45 CFR 170.215 or approved through the 45 CFR 170.405(b)(8) “Standards Version Advancement Process – voluntary updates of certified health IT to newer versions of standards and implementation specifications”?
- **Alternative:** A Participant or Subparticipant who makes a request for access, exchange, or use of EHI via FHIR API will at first make such a request through a QHIN, but in time, a Participant or Subparticipant could directly request access, exchange, or use of EHI via FHIR API standards from another Participant or Subparticipant in a different QHIN.
  - Option 1: We could sunset the API FHIR limitation once all QHINs can support brokered FHIR.
  - Option 2: We could sunset the API FHIR limitation if all QHINs, Participants and Subparticipants support facilitated FHIR exchange.
  - Option 3: We could maintain the exception as is, regardless of FHIR API adoption among TEFCA entities.





# Discussion

Rochelle Prosser, Co-Chair



# Task Force Recommendation Worksheet

Rochelle Prosser, Co-Chair

# Discussion Time



Topic	Time
<b>Information Blocking Enhancements: Protecting Care Access Exception</b>	10 min
<b>Information Blocking Enhancements: Infeasibility Exception</b>	20 min
<b>Information Blocking Enhancements: TEFCA Manner Exception Request for Comments</b>	15 min

# 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*



# Next Steps

Rochelle Prosser, Co-Chair

# Upcoming Meetings

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## Task Force Meeting Date/Time

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)

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## HITAC Meeting Date

8/15 TF provides updates to HITAC

9/12 TF delivers recommendations to HITAC

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**Adjourn**