



# HTI-1 Proposed Rule Task Force 2023

## Group 1: Information Blocking Meeting #10

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

May 16, 2023





# Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

# HTI-1 Proposed Rule Task Force 2023 – Group 1 Roster



Name	Organization
Steven Lane*(Co-Chair/Group 1 Lead)	Health Gorilla
Steven Eichner* (Co-Chair/Group 2 Lead)	Texas Department of State Health Services
Hans Buitendijk*	Oracle Health
Hannah Galvin*	Cambridge Health Alliance
Adi Gundlapalli**	CDC
Deven McGraw*	Invitae Corporation
Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Fillipe Southerland*	Yardi Systems, Inc.
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**      **HTI-1 Proposed Rule Task Force Charge**
- Steven Lane, Co-Chair/Group 1 Lead
  - Steven Eichner, Co-Chair
- 10:40 AM**      **IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events**
- Rachel Nelson, ONC
  - Cassie Weaver, ONC
  - Dan Healy, ONC
- 11:00 AM**      **IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use**
- Rachel Nelson, ONC
  - Cassie Weaver, ONC
  - Dan Healy, ONC
- 11:40 AM**      **Planning for May 17th HITAC Meeting Task Force Update**
- Steven Lane, Co-Chair/Group 1 Lead
  - Steven Eichner, Co-Chair
- 11:50 AM**      **Public Comment**
- Mike Berry, Designated Federal Officer, ONC
- 12:00 PM**      **Adjourn**



# HTI-1 Proposed Rule Task Force Charge

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, 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 – Group 1 Topics

- 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





IB Infeasibility Exception:

Revise Existing Condition: Uncontrollable Events

Proposed New Condition: Third Party Seeking Modification Use

**HTI-1 Proposed Rule Subgroup 1**

Presented by Cassie Weaver, Dan Healy, and Rachel Nelson

May 16, 2023





## Disclaimer and Public Comment Guidance

- The materials contained in this document are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this document is not a legal document. The official proposals are contained in the proposed rule. Please note that other Federal, state and local laws may also apply.
- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.
- This communication is produced and disseminated at U.S. taxpayer expense

# Agenda

- Policy Overview
- Context and Background
- Proposals
- IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events
- IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use





# Background & Context for Proposals



## Proposals Discussed Today

- ONC proposes to revise the “uncontrollable events” condition of the Infeasibility Exception to information blocking in § 171.204(a)(1)
- ONC proposes to renumber the Infeasibility Exception’s (§ 171.204) “infeasible under the circumstances” condition from paragraph (a)(3) to paragraph (a)(5), and to codify at (a)(3) a new condition, “third party seeking modification use.”

# Background: Revise Existing Condition: Uncontrollable Events

- In § 171.204, we created an exception under which an actor's practice of not fulfilling a request to access, exchange, or use EHI “due to” the infeasibility of the request would not be considered information blocking. In the preamble of the ONC Cures Act Final Rule ([85 FR 25867](#)), we specified that there may be situations when complying with a request for access, exchange, or use of EHI would be considered infeasible because an actor is unable to provide such access, exchange, or use due to unforeseeable or unavoidable circumstances outside the actor's control.
  - As examples, we noted an actor could seek coverage under the Infeasibility Exception if it was unable to provide access, exchange, or use of EHI due to a natural disaster (such as a hurricane, tornado, or earthquake) or war. Importantly, we noted that the actor would need to produce evidence and ultimately prove that complying with the request for access, exchange, or use of EHI in the manner requested would have imposed a clearly unreasonable burden on the actor under the circumstances ([85 FR 25866](#)).
- As part of revisions to add clarity to the Infeasibility Exception in the ONC Cures Act Final Rule, we established the “standalone” *uncontrollable events* condition of the Infeasibility Exception in § 171.204(a)(1). Under the uncontrollable events condition, an actor's practice of not fulfilling a request to access, exchange, or use EHI as a result of a natural or human-made disaster, public health emergency, public safety, incident war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority (§ 171.204(a)(1); [85 FR 25874](#)) will not be considered information blocking provided such practice also meets the condition in § 171.204(b).

# Context: Revise Existing Condition: Uncontrollable Events

- The fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception. Rather, the use of the words “due to” in the condition was intended to convey, consistent with the ONC Cures Act Proposed Rule, and does convey that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.
  - To illustrate, a public health emergency is listed as an uncontrollable event under § 171.204(a)(1). If the Federal Government or a state government were to declare a public health emergency, the mere fact of that declaration would not suffice for an actor to meet the condition. To meet the condition, the actor would need to demonstrate that the public health emergency actually caused the actor to be unable to provide access, exchange, or use of EHI for the facts and circumstances in question.
  - The emergency need not be the *only* cause of a particular incapacity, but the actor needs to demonstrate that the public health emergency did in fact negatively impact the feasibility of that actor fulfilling access, exchange, or use in the specific circumstances where the actor is claiming infeasibility.



# Background: New Condition: Third Party Seeking Modification Use

## Current Infeasibility Exception Conditions

**(b) *Responding to requests*** (must be met in complement to at least 1 condition from paragraph (a) – no change proposed)

**(a)(1) *Uncontrollable events***...

**(a)(2) *Segmentation*** (no change proposed)

**(a)(3) *Infeasible under the circumstances*** (proposed to be redesignated at (a)(5); substance unchanged)

- To meet *infeasible under the circumstances*, actor must demonstrate six separate factors that led to its determination that complying with the request would be infeasible under the circumstances.
  - type of EHI and purpose; cost to the actor; financial and technical resources available to the actor; non-discriminatory practice; control over predominant technology; why the actor was unable to provide the EHI in an alternative manner.





## Background: New Condition: Third Party Seeking Modification Use

- We propose to codify at paragraph (a)(3) a new condition (option for satisfying) the Infeasibility Exception to information blocking: “third party seeking modification use.”
- The proposed § 171.204(a)(3) *third party seeking modification use* condition would apply in certain situations where the actor is asked to provide the ability for a third party (or its technology, such as an application) to modify EHI that is maintained by or for an entity that has deployed health information technology as defined in § 170.102 and maintains within or through use of that technology any instance(s) of any electronic health information as defined in § 171.102.
- We propose that the third party seeking modification use condition of the infeasibility exception would be limited to situations when “[t]he request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality), provided the request is not from a health care provider requesting such use from an actor that is its business associate” (proposed new § 171.204(a)(3), emphasis added).

# Context: New Condition: Third Party Seeking Modification Use

## Would be

**Available** where the actor is asked to provide the ability for a third party (or its technology, such as an application) to modify EHI that is maintained by or for an entity that has deployed health information technology as defined in § 170.102 and maintains within or through use of that technology any instance(s) of any electronic health information as defined in § 171.102.

**Not** available when the request is from a health care provider requesting (directly, or through another business associate of the same health care provider) such modification use from an actor that is its business associate.





# Proposed Revisions

# Revise Existing Condition: Uncontrollable Events – Proposed Update

## Proposal

Revise the condition by replacing the words “due to” with “because of” to make clear that a causal connection is needed to use this exception

- The fact that an uncontrollable event occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.
- The use of the words “due to” in the condition conveys that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.

## Benefits

- Makes clear that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.
- Makes clear that the fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.



# Revise Existing Condition: Uncontrollable Events – Proposed Regulation Text

## § 171.204

Infeasibility exception—When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

(a) \* \* \* (1) *Uncontrollable events*. The actor cannot fulfill the request for access, exchange, or use of electronic health information because of a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.

# New Condition: Third Party Seeking Modification Use – Proposed Update

## Proposal

A request to enable one or more third parties to modify EHI (including but not limited to creation and deletion functionality) could be considered infeasible unless the request is from a health care provider requesting such use from an actor that is its business associate.

## Benefits

Reduces actor burden and uncertainty.

- Less documentation requirements compared under the “infeasible under the circumstances” condition
- No need to determine if another exception applies to the request, such as the Security Exception.

Note: Where not applicable, other 171.204(a) conditions (such as existing *infeasible under the circumstances*), might still apply.

# New Condition: Third Party Seeking Modification Use – Proposed Regulation Text

## § 171.204

Infeasibility exception—When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

(3) *Third party seeking modification use.* The request is to enable use of EHI in order to modify EHI (including but not limited to creation and deletion functionality) provided the request is not from a health care provider requesting such use from an actor that is its business associate.



# Discussion

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair



# HTI-1 Proposed Rule Task Force 2023 – Group 1

## Enhance information sharing under the information blocking regulations

- IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events
- IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use





# Planning for May 17th HITAC Meeting Task Force Update

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair



# Task Force Topics Worksheet

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, 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](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*



# Upcoming Meetings – Group 1

Month	Task Force/HITAC Meeting Dates	Task Force Topics
	<b>5/17 (HITAC)</b>	<ul style="list-style-type: none"> <li>• <b>TF Update</b></li> </ul>
	5/23	<ul style="list-style-type: none"> <li>• IB Infeasibility Exception Proposals</li> <li>• New Condition: Manner Exception Exhausted</li> </ul>
	5/30	<ul style="list-style-type: none"> <li>• IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access</li> </ul>
June	6/6 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/7 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/8 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	6/13 (Full TF)	<ul style="list-style-type: none"> <li>• Develop transmittal report/slides</li> </ul>
	<b>6/15 (HITAC)</b>	<ul style="list-style-type: none"> <li>• <b>Final Recommendation and Vote</b></li> </ul>

# HTI-1 Requests for Information Topics by Group

## Group 1 – Information Blocking (IB)

- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

## Group 3 – ONC Health IT Certification Program Updates– Insights Condition, Standards Updates, and RFIs

- Laboratory Data Interoperability Request for Information
- Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities
- FHIR Subscriptions Request for Information
- Clinical Decision Support Hooks Request for Information
- FHIR Standard for Scheduling Request for Information
- SMART Health Links Request for Information





**Adjourn**