



HTI-1 Proposed Rule Task Force 2023

Group 1: Information Blocking Meeting #13

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

May 23, 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: New Condition: Manner Exception Exhausted**
- Rachel Nelson, ONC
 - Cassie Weaver, ONC
 - Dan Healy, ONC
- 11:20 AM** **Request for Information: Health IT Capabilities for Data Segmentation and User/Patient Access**
- Rachel Nelson, ONC
 - Cassie Weaver, ONC
 - Dan Healy, ONC
 - Mohammad Jafari
- 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 Proposed New Condition: Manner
Exception Exhausted

Request for Information: Health IT Capabilities for Data
Segmentation and User/Patient Access

HTI-1 Proposed Rule Subgroup 1

Presented by Cassie Weaver, Dan Healy, and Rachel Nelson

May 23, 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
- IB Infeasibility Exception Proposal: New Condition: Manner Exception Exhausted
- Request for Information: Health IT Capabilities for Data Segmentation and User/Patient Access





Background & Context for Proposals

Proposal Discussed Today

- ONC proposes to codify in paragraph (a) of the Infeasibility Exception (45 CFR 171.204) a new “manner exception exhausted” condition.



Background and Context: Proposed New Condition: Manner Exception Exhausted

- We propose to renumber one existing condition of the Infeasibility Exception and to make substantive revisions including addition of a new *manner exception exhausted* condition that would align with and advance the policy goal of fostering the use of standards-based interoperability in achieving access, exchange, and use of EHI.
- We have received feedback that actors are uncertain as to whether they have satisfied the *infeasible under the circumstances* condition in instances where they believe that fulfilling a request for access, exchange, or use of EHI is infeasible. Specifically, actors have expressed concern about circumstances where the actor's inability to satisfy the Manner Exception's conditions rests solely on the requestor refusing to accept access, exchange, or use in *any* manner consistent with § 171.301 and fulfilling the request in the manner requested would, in the view of the actor, require substantial technical or financial resources — including significant opportunity costs.
- We believe this new § 171.204(a)(4) *manner exception exhausted* condition ensures that a reasonable and necessary practice would not be considered information blocking and strikes the proper balance in achieving the information blocking policies and goals for removing barriers to the access, exchange, and use of EHI, advancing interoperability, and promoting innovation and competition.





Infeasibility Exception Proposed New Condition: Manner Exception Exhausted

Current Infeasibility Exception Conditions

- (1) Uncontrollable events...
- (2) Segmentation...
- (5) Infeasible under the circumstances....

Proposed New Infeasibility Conditions

- (3) Third party seeking modification use
- (4) Manner exception exhausted**

Infeasibility Exception Proposed New Condition: Manner Exception Exhausted

Proposal – Three Part Test

1. The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;
2. The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and
 - Alternative Proposal for # 2 discussed in preamble: “as few as two alternative manners”
- 3. The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.**
 - *Currently provides*
 - *Same*
 - *Substantial number*
 - *Similarly Situated*

Benefits

- Provides certainty (do not have to demonstrate infeasibility under the circumstances)
- Reduces inappropriate or unnecessary diversion of actor resources
- Ensures actors reasonably allocate resources toward interoperable, standards-based manners



Proposed Revisions

Proposed New Condition: Manner Exception Exhausted – Proposed Regulation Text

Proposed Regulation Text

§ 171.204

(4) *Manner exception exhausted.* The actor is unable to fulfill a request for access, exchange, or use of electronic health information because paragraphs (i), (ii), and (iii) are all true.

(i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;

(ii) The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and

(iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.



Request for Information

Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

- ONC believes that data segmentation is an integral capability for enabling the access, exchange, and use of electronic health information ([85 FR 25705](#)). While initiatives such as security tagging capabilities represent an initial step towards enabling appropriate access, exchange, and use of health information in accordance with applicable law and patient preferences, many additional data segmentation challenges remain.
- We have received public feedback indicating that there is significant variability in health IT products' capabilities to segment data, notably including enabling differing levels of access to data based on the user and purpose. There are many situations in which segmentation of data may be required or requested, including use cases where special handling or other restriction of access, exchange, or use of particular portion(s) of a patient's EHI is required by law or consistent with an individual patient's expressed preference regarding their own or others' access to their EHI.





Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

- We seek comment to inform steps we might consider taking to improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI.
- We seek comment related to the capabilities of health IT products to segment data and support health care providers (and actors) in sharing information consistent with patient preferences and all laws applicable to the creation, collection, access, exchange, use and disclosure of EHI.
- We also seek comment on experiences with the availability and utility of certified health IT products' capabilities to segment data in use cases including but not limited to the examples provided in the proposed rule.
- We also seek comment on how greater consistency in provider documentation practices could enhance the feasibility of technical segmentation solutions, and on barriers to technical feasibility presented by local, state, and federal regulations.

Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

- Through public forums and correspondence with ONC, interested parties in the healthcare community have conveyed that their certified health IT lacks capabilities to differentiate the timing of release of certain EHI based on patients' individual preferences. Some interested parties have also indicated that their certified health IT may have little or no ability to restrict a patient's personal representative's access to only some of the patient's EHI using electronic means such as a portal or API or to hold back only some pieces of the patient's EHI, in response to or at the patient's request, while honoring the patient's simultaneous preference for the rest of their EHI to be shared with another of their health care providers.
 - For example, patients may express a preference for a delay in the availability of information to them (such as in a health care provider's patient portal).
 - Or, for another example, an actor could choose to honor a patient request that the actor withhold certain information from particular access, exchange, or use consistent with the individual right to request restrictions under the HIPAA Privacy Rule and the information blocking Privacy Exception.^[418]

Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

- We seek to support information blocking actors' efforts to honor patients' expressed preferences that other law allows the actor to honor as well as actors' needs to comply with all applicable tribal, state, and federal laws restricting or placing specific preconditions on permissibility of information access (release of information) and sharing in situations (or “use cases”) such as those described in the non-exhaustive examples below.
 - A health care provider needs to prove or validate consent of the patient (by electronic or manual means) regarding EHI subject to the Confidentiality of Substance Use Disorder Patient Records regulations, [42 CFR part 2](#)—or other federal law or applicable state or tribal law with specific consent requirements—prior to sharing it with another health care provider treating the same patient for other clinical concerns.
 - A health care provider needs to identify and segment from particular access, exchange, or use by specific entities for specific purposes data subject to varying state laws requiring special handling or access restrictions in such situations—such as behavioral health information, HIV diagnosis and treatment, genetic testing, treatment of minors, or incidents of sexual violence.
 - An actor's practice meets the conditions of the Preventing Harm Exception (§ 171.201) for withholding EHI for access, exchange, or use—such as access by the patient or by a particular personal representative of the patient—of *some*, but not all, of the EHI the actor has for a particular patient.

Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

- It is ONC's impression that at least some health care providers and their patients sometimes encounter challenges or technical limitations as they work to provide patients or their personal representatives with electronic access to the information they want when they want it. Examples of these challenges include, but are not necessarily limited to:
 - A certified EHR (certified health IT) currently in use by a health care provider that is, as implemented, capable only of "all or nothing" release of all EHI test results for all patients immediately to the patient portal, without offering the ordering clinicians or other healthcare professionals using the certified EHR any capability to flag or withhold individual EHI test results for an individual patient from the patient portal.
 - A health care provider's current certified EHR is designed and implemented such that any test result the patient and health care provider want to have available to the patient in the portal must be manually pushed to the portal, result by result, by the ordering clinician.
 - Existing segmentation tools or modalities (for example, implementation of segmentation capabilities only by broad data class rather than at the level of individual data point) not providing enough flexibility to address more complex use cases, such as honoring a patient's request to have immediate access to most of their EHI but to have electronic access to some EHI, such as test results, that are complicated to interpret or indicate a potential of a life-limiting diagnosis, only after such results have been explained to them in real time by an appropriately qualified healthcare professional.

Group 2 Topic for Wednesday 5/24: Proposal: Patient Requested Restrictions Criterion in § 170.315(d)(14)

In [section III.C.10](#) of the proposed rule, we propose a new certification criterion specifically focused on supporting patient preferences related to their right to request a restriction on certain uses and disclosures of their PHI under the HIPAA Privacy Rule (see [45 CFR 164.522](#)).

This proposed functionality is focused specifically on supporting one health IT enabled mechanism for a patient to request a restriction on disclosure and for a covered entity to honor that restriction using a certified Health IT Module (See [section III.C.10](#) of the Proposed Rule for further detail).

This proposal will be discussed on the Wednesday 5/24 meeting of task force group 2, where the SMEs responsible for drafting the proposal will speak to the task force. If interested, group 1 members are welcome to attend group 2's meeting on Wednesday 5/24.





How to Submit a Comment

How to Submit a Comment Online



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PR Proposed Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

A Proposed Rule by the Health and Human Services Department on 04/18/2023

This document has a comment period that ends in 53 days. (06/20/2023)

SUBMIT A FORMAL COMMENT

2 comments received. View posted comments

PUBLISHED DOCUMENT

Start Printed Page 23746

AGENCY:
Office of the National Coordinator for Health Information Technology (ONC),
Department of Health and Human Services (HHS).

ACTION:
Proposed rule.

SUMMARY:
This proposed rule would implement the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
04/18/2023

Agencies:
Department of Health and Human Services
Office of the Secretary

Dates:
To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on June 20, 2023.

Comments Close:
06/20/2023

From the [HTI-1 Proposed Rule](#) on FederalRegister.gov, just click the **Submit a Formal Comment** button

Or, at <http://www.regulations.gov> search by Federal Register docket number **2023-07229**

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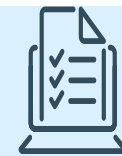
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Request for Information: Health IT Capabilities for Data Segmentation and User/Patient Access

Mohammad Jafari



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





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

*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
	5/30	<ul style="list-style-type: none"> Review draft recommendations & thoughts to date
June	6/6 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/7 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/8 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/13 (Full TF)	<ul style="list-style-type: none"> Develop transmittal report/slides
	6/15 (HITAC)	<ul style="list-style-type: none"> Final Recommendation and Vote



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