



HTI-1 Proposed Rule Task Force 2023

Group 1: Information Blocking Meeting #7

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

May 9, 2023





Call to Order/Roll Call

Wendy Noboa, Acting 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) | 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

- Wendy Noboa, Acting 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 Manner Exception – TEFCA Manner Proposal

- Dan Healy, ONC
- Cassie Weaver, ONC

11:20 AM IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

- Dan Healy, ONC
- Cassie Weaver, 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

- Wendy Noboa, Acting 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 Manner Exception – TEFCA Manner Proposal and IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

HTI-1 Proposed Rule Subgroup 1

Presented by Dan Healy and Cassie Weaver

May 9, 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 Manner Exception – TEFCA Manner Proposal
- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities





Background & Context for Proposals



Proposal and RFI Discussed Today

- ONC proposes to add a TEFCA Manner condition (option) to the proposed revised and renamed Manner Exception, to be codified in 45 CFR 171.301(c). (“TEFCA Manner proposal”)
- In parallel to the Manner Exception proposal, we propose to define in paragraph (d) of 45 CFR 171.301 terms used in the TEFCA Manner condition
- The HTI-1 proposed rule also includes a request for information (RFI) on possible additional TEFCA reasonable and necessary activities. (“IB RFI 2”)



Background: TEFCA Manner Proposal (slide 1 of 2)

- In the ONC Cures Act Proposed Rule ([84 FR 7552](#)), we requested comments on whether we should propose, in a future rulemaking, a narrow exception to the information blocking definition for practices that are necessary to comply with the requirements of the Common Agreement. We stated that such an exception may support adoption of the Common Agreement and may encourage other entities to participate in trusted exchange through HINs that enter into the Common Agreement.
- We discussed that it would do so by providing protection if there are practices that are expressly required by the Common Agreement, or that are necessary to implement Common Agreement requirements, that might implicate the information blocking definition and would not qualify for another exception. We noted that such an exception would be consistent with the complementary roles of the information blocking provision and other provisions of the Cures Act that support interoperability and enhance the trusted exchange of EHI (including the interoperable network exchange provisions ([42 U.S.C. 300jj–11\(c\)\(9\)](#)), the definition of interoperability ([42 U.S.C. 300jj\(9\)](#)), and the conditions of certification in [42 U.S.C. 300jj–11\(c\)\(5\)\(D\)](#)).
- We further noted that we expected that any proposal would be narrowly framed such that contract terms, policies, or other practices that are not strictly necessary to comply with the Common Agreement would not qualify for the exception. Similarly, we expected that any future proposal would provide that an actor could benefit from this exception only if the practice or practices that the actor pursued were no broader than necessary under the circumstances. We commented that these limitations would ensure that the exception would be narrowly tailored to practices that are most likely to promote trusted exchange without unnecessarily impeding access, exchange, or use of EHI.



Background: TEFCA Manner Proposal (slide 2 of 2)

- A majority of commenters asserted that there should be some form of “safe harbor” for TEFCA participants, while other commenters contended that such an approach was unwarranted and that all actors should be subject to the same information blocking policies and requirements. Overall, comments received in response to the Cures Rule RFI that were in favor of an exception outnumbered those that were not in favor. Some commenters advocating for an exception covering or incentivizing TEFCA participation noted that such an exception would provide certainty and reduce the compliance burden for the market.
- The HITAC's recommendation regarding the Cures Rule RFI urged ONC “to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors” and expressed a view that a careful balance needed to be struck between encouraging compliance with the information blocking regulations, potentially through the adoption of TEFCA, and the need to investigate information blocking practices and not inadvertently allow “bad actors” to circumvent compliance with the information blocking regulations.
- During the development of TEFCA and since the publication of the Common Agreement on January 19, 2022, ONC has continued to receive requests for clarification regarding the potential information blocking implications or interpretations of practices (actions or omissions) that the Common Agreement requires of QHINs, and of Participants or Subparticipants through the Common Agreement's required flow-down provisions in Participant-QHIN or Participant-Subparticipant Agreements (also referred to as Framework Agreements). Interested parties have continued to request that ONC provide certainty that such practices would be considered reasonable and necessary activities that do not constitute information blocking.



Context: TEFCA Manner Proposal (slide 1 of 3)

- Each QHIN, Participant, or Subparticipant has chosen to become a part of the TEFCA ecosystem. Where mechanisms consistent with TEFCA's technical framework and other requirements relevant to particular type(s) of EHI and purpose(s) of exchange *can* support EHI access, exchange, use for *any* purpose permitted under the Common Agreement and applicable Framework Agreement(s), we believe it is reasonable and necessary for actors who have chosen to become part of the TEFCA ecosystem to prioritize use of these mechanisms rather than other mechanisms—that are potentially less interoperable, less secure, or less scalable—for sharing EHI with requestors who have also chosen to become part of the TEFCA ecosystem.
- Proposal aligns with a foundational policy construct underpinning the Manner Exception: it facilitates an actor reaching agreeable terms with a requestor and acknowledges that certain agreements have been reached for the access, exchange, and use of EHI.
- Proposal incorporates multiple aspects responsive to public comments and feedback received on the ONC Cures Act Proposed Rule ([84 FR 7424](#)).



Context: TEFCA Manner Proposal (slide 2 of 3)

- To illustrate the proposed TEFCA Manner condition: if a responding actor fulfills a request to access, exchange, or use EHI from a QHIN, Participant, or Subparticipant through TEFCA means, then that would be sufficient for meeting this proposed new condition.
 - In this scenario, the responding actor would not be required to conform any fees or any license agreements to the Fees or Licensing Exceptions ([45 CFR 171.302](#) and [171.303](#), respectively)
 - TEFCA Manner condition could be satisfied regardless of whether the requesting QHIN, Participant, or Subparticipant initially requested access, exchange, or use through TEFCA means or another manner.
- Another important feature of the proposed TEFCA condition is that it can be satisfied by the responding QHIN, Participant, or Subparticipant either fulfilling or *offering to fulfill* the requesting QHIN's, Participant's, or Subparticipant's request for EHI using TEFCA means. To illustrate this feature —
 - If a QHIN, Participant, or Subparticipant actor *offers* to fulfill a request to access, exchange, or use EHI from a QHIN, Participant, or Subparticipant through TEFCA means that are available to both the requestor and responding actor, then that would be sufficient for meeting this proposed new TEFCA Manner condition, even if requesting QHIN, Participant, or Subparticipant:
 - initially requested access, exchange, or use in some other manner; or
 - refused to accept the responding actor's offer to fulfill the requested EHI access, exchange, or use through TEFCA means.



Context: TEFCA Manner Proposal (slide 3 of 3)

- TEFCA Manner condition would be an additional option under the revised and renamed Manner Exception; the Manner Requested and Alternative Manner conditions would also remain available to QHINs, Participants, or Subparticipants responding to any requestors.
- The establishment of the TEFCA condition would not preclude a QHIN, Participant, or Subparticipant information blocking actor from making a different choice with respect to supporting non-TEFCA means in complement to TEFCA means of information sharing with others who choose to become QHINs, Participants, and Subparticipants.



Proposed Revisions



TEFCA Manner Proposal – Summary

- The proposed TEFCA manner exception would identify as reasonable and necessary an information blocking actor's practice of prioritizing using, in lieu of other feasible manners, the appropriate TEFCA means:
 - for any and all EHI for which access, exchange, or use can be supported by TEFCA means for both the actor and requestor;
 - so long as the requestor is a QHIN, Participant, or Subparticipant and the purpose of the access, exchange, or use is permitted under the TEFCA governing agreements;
 - regardless of whether the request is initially made through TEFCA means or otherwise; and
 - regardless of whether all of the particular data class(es) or exchange purpose(s) requested are yet *required* by TEFCA's governing agreements to be returned in response to a TEFCA request.
- In order to satisfy this condition, we are considering requiring that an actor would need to check an available directory of all QHINs, Participants, and Subparticipants under the TEFCA governing agreements in order see if the requestor is listed.
 - While the listing or non-listing of a requestor in such a directory would not be dispositive as to the truth of the matter, an actor checking the directory would likely improve the efficiency of such interactions (*i.e.*, EHI requests and responses) and would help inform the assessment of the actor's intent under the circumstances.
 - We welcome comments on this potential requirement of the proposed new TEFCA Manner condition.

IB Manner Exception – Renumbered Existing Manner Requested and Alternative Manner Conditions

§ 171.301

Manner exception—When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested.*

- (1) An actor must fulfill a request for electronic health information in any manner requested, unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested.
- (2) If an actor fulfills a request for electronic health information in any manner requested:
 - (i) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and
 - (ii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(b) *Alternative manner.* If an actor does not fulfill a request for electronic health information in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested, the actor must fulfill the request in an alternative manner, as follows:

- (1) The actor must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph (b)(1)(i) of this section and only proceeding to the next consecutive paragraph if the actor is technically unable to fulfill the request in the manner identified in a paragraph.
 - (i) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.
 - (ii) Using content and transport standards specified by the requestor and published by:
 - (A) The Federal Government; or
 - (B) A standards developing organization accredited by the American National Standards Institute.
 - (iii) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor.
- (2) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302.
- (3) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

IB Manner Exception – TEFCA Manner Proposal (Slide 1 of 2)

(c) *TEFCA manner.* If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted under the Common Agreement and Framework Agreement(s) from any other QHIN, Participant, or Subparticipant using Connectivity Services, QHIN Services, or the specified technical services in the applicable Framework Agreement available to both parties, then:

- (i) The actor is not required to offer the EHI in any alternative manner;
- (ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and
- (iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.



IB Manner Exception – TEFCA Manner Proposal

Definition (Slide 2 of 2)

(d) *Definitions.* The terms used in paragraph (c) of this section shall have the following meanings.

(1)(i) *Qualified Health Information Network (QHIN)* means a Health Information Network that is a U.S. Entity that has been Designated by the Recognized Coordinating Entity (RCE) and is a party to the Common Agreement countersigned by the RCE.

(ii) *Participant* means a U.S. Entity regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

(iii) *Subparticipant* means a U.S. Entity regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either:

(A) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive information; or

(B) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used of the Common Agreement to send and/or receive information.

(iv) *Connectivity Services* means the technical services provided by a QHIN.

(v) *Framework Agreement(s)* means any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

(2) *QHIN Services* means any technical services provided within a QHIN.



IB RFI – Possible Additional TEFCA Reasonable and Necessary Activities

We seek comment on whether any other particular practices that are not otherwise required by law but are required of an individual person or entity by virtue of their status as a QHIN, Participant, or Subparticipant pursuant to the Common Agreement pose a substantial concern or uncertainty regarding whether such practices *could* constitute information blocking as defined in [45 CFR 171.103](#). As a reminder, to constitute information blocking as defined in [45 CFR 171.103](#), the practice that is not required by law would have to be done with the requisite knowledge on the part of the actor engaging in the practice, would have to rise to the level of an interference, and not be covered by an existing information blocking exception—including but not limited to the Manner Exception as we propose to modify it.

We seek comment on what, if any, particular practices required of QHINs, Participants, or Subparticipants may pose such concerns or uncertainty, and the specific source of the requirement, obligation, or commitment to engage in the practice—such as the Common Agreement, flow-down requirements in Framework Agreements, the QHIN Technical Framework, or Standard Operating Procedures published by the ONC Recognized Coordinating Entity (RCE).

We also request that commenters identify which practices they believe are not covered by existing information blocking exceptions and that commenters would advocate we assess for potential identification as reasonable and necessary activities that do not constitute information blocking as defined in [45 CFR 171.103](#). Recognizing that not all individuals or entities who may have a right or be allowed under applicable law to access, exchange, or use EHI may be in a position to become a QHIN, Participant, or Subparticipant, we also seek comment on whether and how any such identification of additional reasonable and necessary activities might pose concerns about unintended consequences for EHI access, exchange, or use by individuals or entities who are not QHINs, Participants, or Subparticipants.



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 Manner Exception – TEFCA Manner Proposal
- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities





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

*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 |
|-------|--------------------------------|---|
| | 5/16 | <ul style="list-style-type: none"> • IB Infeasibility Exception Proposals <ul style="list-style-type: none"> ○ Revise Existing Condition: Uncontrollable Events ○ New Condition: Third Party Seeking Modification Use |
| | 5/17 (HITAC) | <ul style="list-style-type: none"> • TF Update |
| | 5/23 | <ul style="list-style-type: none"> • IB Infeasibility Exception Proposals • New Condition: Manner Exception Exhausted |
| | 5/30 | <ul style="list-style-type: none"> • IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access |
| 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 |



Adjourn