



Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 1: Information Blocking

Meeting Notes | May 9, 2023, 10:30 AM - 12 PM ET

Executive Summary

The focus of the Group 1 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 9 was to discuss information blocking (IB) manner exceptions in the Trusted Exchange Framework and Common Agreement (TEFCA) manner proposal, walk through the IB request for information (RFI) 2 regarding possible additional TEFCA activities, and plan for the May 17th Health Information Technology Advisory Committee (HITAC) meeting Task Force update.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	IB Manner Exception – TEFCA Manner Proposal
11:20 AM	IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
11:40 AM	Planning for May 17 th HITAC Meeting Task Force Update
11:50 AM	Public Comment
12:00 PM	Adjourn

Call to Order

Wendy Noboa, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 AM.

Roll Call

Members in Attendance

Steven Lane, Health Gorilla, Co-Chair, Group 1 Lead Steven Eichner, Texas Department of State Health Services, Co-Chair Hans Buitendijk, Oracle Health Hannah Galvin, Cambridge Health Alliance Adi Gundlapalli, CDC Deven McGraw, Invitae Corporation Filipe (Fil) Southerland, Yardi Systems, Inc.

Members Not in Attendance

Eliel Oliveira, Dell Medical School, University of Texas at Austin Sheryl Turney, Elevance Health



ONC Staff

Wendy Noboa, Acting Designated Federal Officer, ONC Daniel Healy, ONC Sara McGhee, ONC Rachel Nelson, ONC Cassie Weaver, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge

HTI-1 Proposed Rule Task Force (Task Force) co-chairs, Steven Eichner and Steven Lane, welcomed Group 1 attendees. Group 1 lead, Steven Lane, reviewed the meeting agenda and charge detailed in the <u>May 9</u> meeting presentation materials.

IB Manner Exception – TEFCA Manner Proposal

Daniel Healy, ONC, provided background on the IB manner proposal for the TEFCA manner proposal.

Discussion:

- Deven McGraw asked Daniel if he could clarify how TEFCA and non-TEFCA entities share information.
 - Daniel said he focuses on the term "supporting" in the rule. If there are two entities
 participating in TEFCA, that fits the condition required to exchange. However, that being in
 place does not preclude those entities from supporting and utilizing non-TEFCA methods of
 exchange.

IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

Cassie Weaver, ONC, walked through the proposed revisions, the summary of the TEFCA manner proposal, IB manner exceptions, and the IB RFI.

Discussion:

- Steven Lane said if there is terminology used that requires TEFCA exchange, even before purposes of use are fully defined through Standard operating Procedures (SOPs), then it may disincentivize participation in TEFCA. What are the limitations of that extension? Will the permitted purposes be fully defined by the time the rule goes into place?
 - Cassie noted that would be a good item to add to the recommendations document. A reasonable and necessary activity could be seen as a disincentive to participate in TEFCA. ONC is happy to consider those questions.
- Steven Eichner noted some organizations cannot implement TEFCA, e.g., public health systems. There is currently no formal documentation or processes laid out at this time. How will that gap be addressed?
 - Cassie noted ONC is aware of the lack of documentation and processes. TEFCA standard operating procedures (SOPs) and proposed rules still won't become final for a few years. In



some ways, TEFCA will have to catch up with rulemaking.

- Hans Buitendijk said participants in Qualified Health Information Networks (QHINs) may not utilize TEFCA for all of their information exchange. Is the rule written in a way where QHINs must support all purposes of exchange before being compliant with TEFCA?
 - Rachel Nelson said ONC cannot clarify that intent. However, she noted the current text does not say that the responding actor would need to support everything.
- Deven McGraw clarified if the requester and the data holder are participants in TEFCA, then the limitation in the fees exception and licensing exception would not apply. What is the impact of TEFCA access on individual access?
 - Cassie said that was correct; the licensing and fees limitations would not apply.
 - Rachel Nelson noted the condition of this exception would continue. If an app wants to be set up as an "individual access provider" under TEFCA, there would be stipulations for how participants can interact with it. Those exceptions may not apply if the app decided to go down a different path.
 - Deven said this is worth further consideration, but it may disincentivize organizations from utilizing TEFCA if it translates into the potential for higher fees.
- Steven Lane said the fee question could potentially go either way. Would this new manner proposal lead to higher fees, or would it prevent the charging of fees?
 - Cassie said the language is the same in the IB manner exception.
- Hannah Galvin noted the purpose behind this is to encourage participation in TEFCA. It is still early in the process, and SOPs have not been tested. She has further questions about implementation that she will list in the recommendations document.
- Steven Eichner asked if there are exceptions that apply to participants and sub-participants within a single QHIN? Or is this rule focused on exchanges between QHINs?
 - Steven Lane said if two participants are in the same QHIN, it should not differentiate. He suggested Steven Eichner include that comment in the recommendations document.
- Deven noted it would be interesting to hear the Sequoia Project's thoughts on this.
- Hannah added the Task Force will not know the extent of all the gaps are until TEFCA is implemented. She is interested to see what happens in the next 24 months as this moves forward.

Planning for May 17th HITAC Meeting Task Force Update

Steven Lane encouraged the Task Force to continue adding comments in the recommendations document. He reminded the group that this group will meet on the 16th, and the HITAC meeting will be the following day. The Task Force reviewed the recommendations document.

Discussion:

- Hans said the Task Force should mention the notion of "outsourcing use of consultants" during the HITAC meeting.
- Deven did not think there is anything that the workgroup has discussed that has been controversial and needs to be flagged to the HITAC.

PUBLIC COMMENT

Wendy Noboa opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

Zoe Barber noted the current definitions of "connectivity services" may change. She said it is unclear if the exchange is intended to happen under the legal framework. She requested clarification on the technical and legal structures.



QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: Key point: "any purpose PERMITTED under TEFCA, as opposed to those purposes for which a response is REQUIRED under TEFCA.

Hans Buitendijk: To what extent do you have to support all permitted Exchange purposes to claim the exception, vs. the purpose(s) that use the capabilities being requested?

Steven Lane: Please clarify whether the references to the fees and licensing exceptions mean that exchange that might otherwise require a requestor to pay a fee or have a license could avoid such requirement(s) when accessing PHI via TEFCA means.

Deven McGraw: Steven, the exceptions provide limitations on fees and licensing conditions — as I read the proposal, those limitations would not apply when TEFCA is the mechanism of exchange — but would be great to get clarity on that.

Hannah K. Galvin: If exchanging outside of current TEFCA SOP's, how certain can you be that information is being exchanged successfully?

Deven McGraw: - that would include the fee limitations on individual access

Steven (Ike) Eichner: Can you clarify whether the intention is for this to apply to exchanges between Participants or Subparticipants within a single QHIN?

Hannah K. Galvin: I echo Deven's concern. I think we don't yet understand who will become TEFCA subparticipants and how this will work.

Deven McGraw: Ike's question around exchanges within a single QHIN - I have assumed that as long as that exchange is occurring as part of TEFCA, this exception would apply - but helpful to get a gut check on that.

Rachel Nelson: At a certain point, we need to step back and let you all decide what you want to advance to HITAC as potential recommendations.

Rachel Nelson: Sorry, all - I just learned that copy-paste is not a viable solution if my initial comment is set to wrong audience.

Deven McGraw: QHINs are large and definitely facilitate exchange among their participants, and I think that still counts as "TEFCA" exchange — although the parties could each decide to exchange outside of TEFCA per the proposed regulations.

Deven McGraw: +1 to Steven Lane

Zoe Barber: Happy to make some initial comments during public comment period today and participate in a more "formal" manner, if requested

Deven McGraw: Excellent point by Zoe that the exchange needs to be occurring consistent with/pursuant to the framework agreement(s) & policies & procedures....otherwise we could be subjecting requesters to a potentially set of onerous conditions for exchange

Deven McGraw: Spreadsheet goblin

Deven McGraw: Great call! Thanks to the staff and the co-chairs for leading the discussion. Thanks to Zoe for her remarks.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.



Resources

HTI-1 Proposed Rule Task Force 2023 Webpage HTI-1 Proposed Rule Task Force 2023 – May 9, 2023 Meeting Webpage HITAC Calendar Webpage

Adjournment The meeting adjourned at 12:00 PM.