

Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 1: Information Blocking (IB)

Meeting Notes | May 23, 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 23 was to review the Information Blocking (IB) Infeasibility Exception proposal on New Condition: Manner Exception Exhausted. Group 1 also discussed the Request for Information (RFI): Health IT Capabilities for Data Segmentation and User/Patient Access.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Information Blocking Infeasibility Exception Proposal: New Condition: Manner Exception Exhausted
11:20 AM	Request for Information: Health IT Capabilities for Data Segmentation and User/Patient Access
11:50 AM	Public Comment
12:00 PM	Adjourn

Call to Order

Mike Berry, 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
Adi Gundlapalli, CDC (Represented by Sanjeev Tandon)
Deven McGraw, Invitae Corporation
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Sheryl Turney, Elevance Health

Members Not in Attendance

Hans Buitendijk, Oracle Health
Hannah Galvin, Cambridge Health Alliance
Eliel Oliveira, Dell Medical School, University of Texas at Austin



ONC Staff

Mike Berry, Designated Federal Officer, ONC
Daniel Healy, ONC
Michael Lipinski, 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, charge, and Group 1 topics detailed in the [May 23 meeting presentation materials](#).

Information Blocking Infeasibility Exception Proposal: New Condition: Manner Exception Exhausted

Daniel Healy, ONC, reviewed disclaimers and public comment guidance. Cassie Weaver, ONC, reviewed background, infeasibility exception, benefits, and proposed regulation text on the New Condition: Manner Exception Exhausted.

Discussion

- Deven McGraw noted a concern with the “as few as two alternative manners” part of the manner exception exhausted proposal, noting that if an entity doesn’t use certified health IT, one of the three alternative manners described in the current content and manner exception would be off the table.
 - Michael Lipinski, ONC, stated that part of the intent behind the current content and manner exception explained in the preamble is to facilitate parties’ agreement on terms of how EHI is accessed/exchanged/used. If there is no agreement on the part of the requestor to the alternative manner process, then the process moves to the infeasibility exception.
 - Michael noted the proposed exception discussed today does not require agreement from requesters if certain conditions are met.
 - Michael asked Task Force members for proposal comments with a focus on potential consequences of how the modified exception could work.
- Steven Eichner noted they feel that ONC is developing a complex framework that will be difficult for smaller actors to understand and meet the required conditions, particularly those actors who lack the resources to contemplate whether or not an exception may apply.
 - Michael noted that ONC’s proposal attempts to simplify current processes.
- Steven Eichner noted the difficulty in looking at what constitutes a different request when asking for an additional data field.
 - Michael welcomed comments on this topic.
 - Steven Eichner suggested clarity and predictability in thinking about smaller providers who do not have the resources to fulfill all data requests.
- Steven Lane welcomed Task Force members to enter their comments on the working spreadsheet.




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

Daniel Healy, ONC, reviewed the IB RFI: Health IT Capabilities for Data Segmentation and User/Patient Access. Rachel Nelson, ONC, reviewed how to submit a comment on the proposed rule, as well as the May 24 Group 2 meeting topic of Proposal: Patient Requested Restrictions Criterion in § 170.315(d)(14). Rachel recognized this proposal is outside of Group 1's charge and reminded Task Force members that this proposal is available for public comment. Mohammad Jafari discussed feedback and recommendations for the RFI: Health IT Capabilities for Data Segmentation and User/Patient Access.

Discussion

- Steven Lane expressed support for this RFI from an individual and provider level. He also noted
- Steven said that important metadata (for example, documenting an IB exception) ideally should travel with the EHI to other providers/healthcare institutions, so that patients' preferences and providers' clinical decisions can be better implemented across the care journey, even if there is often no current legal requirement (as mentioned by Deven) for this to be the case.
- Steven Lane asked for clarity on the distinction between today's and tomorrow's Task Force RFI/proposal discussions.
 - Rachel Nelson noted the planned May 24 proposal specifically focuses on supporting patient preferences and disclosure of patient data which cross-references HIPAA Privacy Rule 45 CFR 164.522. The RFI being discussed today asks for feedback on additional challenges and opportunities related to data segmentation from a broader perspective.
- Steven Lane discussed Deven McGraw's comment via chat, stating consent policy requirements often do not follow the data when traveling from one site to another.
- Steven noted that when the state/provider determines data requirements, it is advantageous to send data requirements along with the data to other sites.
 - Deven expressed alignment with this comment. Deven noted that metadata tagshave triggers that restrict disclosures in an automated fashion. If this occurs, there could be complications in data sharing.
 - Sheryl agreed with Deven's concerns regarding data tagging. Sheryl noted the importance in understanding data tagging's impact on different stakeholders.
- Sheryl Turner suggested that we consider that certified health IT will exist in the framework of the Trusted Exchange Framework and Common Agreement (TEFCA). Sheryl also suggested patient education regarding the limitations of data exchange.
- Steven Lane discussed Fil Southerland's chat comments on consent duration and the challenge of managing granular revocation and removal of restrictions. In an ideal world, consent changes in one organization would be communicated to all applicable parties.
 - Fil discussed the possible situation in which patients are unaware of previously restricted data agreements and exchanges.
- Steven Eichner stated he is unsure why we don't have greater transparency in disclosures on data information exchange. Patients should have access to data disclosures and what restrictions have been placed in the past on how data is exchanged.
 - Deven suggested that this topic be further discussed in ONC workgroups.
- Steven Lane encouraged Task Force members to insert their comments on the working spreadsheet.
- Steven Lane asked Mohammad to discuss existing technical standards during tomorrow's Group 2 meeting. Mohammad discussed the following standards:
 - Hazard Communication Standard (HCS) standard – This standard is abstract and describes concepts of data labeling. This standard does not provide concrete implementation guidance.
 - Consolidated Clinical Document Architecture Data Segmentation for Privacy (C-CDA DS4P) – This is an old standard.

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- Fast Healthcare Interoperability Resources (FHIR) DS4P – This is a newer standard with value sets that should be included. Mohammad advised a subset of defined terminology be chosen to prevent confusion.

PUBLIC COMMENT

Mike Berry, Designated Federal Officer, ONC, opened the meeting up for public comment.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

- Mark Savage suggested reviewing the 2010 President's Council of Advisors on Science and Technology (PCAST) report for information related to today's topics. Mark noted ongoing discussion of these topics in other forums such as the Gravity Project Implementation Guide (IG) which looked at race, ethnicity, gender, and sexual identity data.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the HTI-1 Proposed Rule Task Force. Meeting materials can be found at: <https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-1-2>

Mike Berry (ONC): Please remember to tag "Everyone" when using Zoom chat. Thank you!

Steven Lane: Would be interested to hear from workgroup members and the public whether being required to offer all three alternative manners would represent a substantially greater burden on data holders than offering two alternative manners.

Deven McGraw: I have some questions on that very point, Steven 😊

Deven McGraw: Staying off video to preserve better internet connectivity

Deven McGraw: Will do, Steven!

Steven Lane: Many actors have been challenged interpreting the current rules. It seems to me that these changes clarify and somewhat simplify the process of documentation under this exception.

Mark Savage: Seems to me that this work on data segmentation may also hold some insights and approaches for reproductive health data in particular post-Dobbs.

Mohammad Jafari: @Mark that is indeed one of the emerging use cases.

Rachel Nelson: Slides from the 5/18 public webinar in accessible PDF, including how-to-comment slides, available now: https://www.healthit.gov/sites/default/files/2023-05/HTI-1%20Proposed%20Rule%205.18%20IB%20Presentation_508.pdf

Deven McGraw: Consent policy requirements often do not “follow the data” (Part 2 data being the exception to that) — so the need to enforce a consent policy in one setting does not necessarily need to be propagated forward from a legal perspective (although there may be a desire to enable this functionality as a benefit to patients even absent a requirement to do so....)

Steven Lane: Great point, Deven. It seems to me that we want this metadata to travel with data that has been tagged, even if there is not an absolute legal requirement to respect the restrictions at the receiving system.

Mark Savage: Suddenly recalling the prescient PCAST report in 2010.

Sheryl Turney: If patient limits data sharing, they may not know that this restriction does not flow down.



Fil Southerland: On a similar note, do consent durations come into play, or do we fully rely on patient revocations? Do we need to couple granular revocation rules with consent/segmentation rules?

Deven McGraw: Agree, Steven, with that ideal in terms of honoring patient restrictions/consent/revocations - but that's not generally how we handle it today.

Deven McGraw: (Honoring downstream, I meant to say)

Deven McGraw: Steve (Ike), the HITECH policy committee looked at this issue, albeit many years ago. The technical capability to distinguish between internal access and external disclosures - and for what purpose for either/both - is not currently a functionality in certified EHRs.

Deven McGraw: Thank you, Mohammad!

Rita Torkzadeh: At HL7 WGM earlier this month Josh Mandel asked Micky how TEFCA will give patients transparency in data disclosures

Deven McGraw: Thanks, Rita - since networks are all about facilitating disclosures (vs. internal access within an organization), it is more feasible from a technical perspective to be able to track network disclosures (at least that's what I've been led to believe). Great point.

Rita Torkzadeh: @Steven it was a question to Micky in the WGM+ session related TEFCA and FAST will and address unintended disclosures

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 23, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

Adjournment

The meeting adjourned at 12:00 PM.