



Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 1: Information Blocking

Meeting Notes | May 30, 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 30 was to discuss and revise the HTI-1 Proposed Rule draft recommendations.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Update and Revise Draft Recommendations
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 Hans Buitendijk, Oracle Health Hannah Galvin, Cambridge Health Alliance Deven McGraw, Invitae Corporation Eliel Oliveira, Dell Medical School, University of Texas at Austin Filipe (Fil) Southerland, Yardi Systems, Inc.

Members Not in Attendance

Adi Gundlapalli, CDC Sheryl Turney, Elevance Health

ONC Staff

Mike Berry, Designated Federal Officer, ONC Daniel Healy, 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 May 30 meeting presentation materials.

Update and Revise Draft Recommendations

Steven Lane reviewed Group 1's HTI-1 Proposed Rule Task Force suggestions in the recommendations document. A robust discussion followed.

Discussion:

- Steven Lane reviewed Row 1 in the recommendations document.
 - Steven Eichner asked if entities not focused on healthcare delivery, e.g., summer camps or non-profits, fall under the provider category in the information blocking rule.
 - Deven McGraw said if the organizations meet the provider definition under Medicare's rules, then they are an information provider and are subject to the regulations under Information Blocking. She is not sure if those organizations meet the definition.
 - o Steven Lane said this question could be referred to the HITAC Annual Report Workgroup.
- No adjustments were made in Row 2 in the document.
- Steven Lane reviewed Row 3 in the recommendations document.
 - Hans Buitendijk commented there is a challenge when an individual meets the criteria of multiple roles. There is confusion when a custom solution developer becomes an offeror of health IT and when a self-developer uses contracted resources. He is unclear about where consultants fit into this category.
 - Steven Eichner said if a consultant is hired to work on staff augmentation, that individual is providing programming services, not health IT.
 - Hans said in this situation, the consultant works under the direction of the provider. Do they
 work under the provider or under their organization (if their organization is an offeror of health
 IT)?
 - Steven Eichner said the language should include "work for hire".
 - The Task Force recommended that a consultant organization providing health information technology (HIT) development "for hire", under the direction of a provider, should be treated like the provider and be considered exempt from offering HIT with respect to the work done, regardless of if they are themselves developers of certified HIT.
- Eliel Oliveira recommended ONC consider the owner of intellectual property in HIT that derives from HIT development.
 - Steven Eichner noted that could get complex.
 - Steven Lane and the Task Force agreed to leave the recommendation as is for now. Eliel is welcome to add his comments into the document.
- Steven Lane reviewed Row 4 in the document.
 - Deven said the current recommendations listed are not compatible with each other. There will be unintended consequences with fees.
 - Hans suggested changing the recommendation to include the availability of a qualified health information network (QHIN). He agreed with the intent but recommended holding off on a formal recommendation for now.
 - Steven Lane said once the standard operating procedures (SOPs) are approved, organizations will be notified when exchange will be required.

- Steven Eichner said availability of exchange between QHINs does not necessarily mean that participants can ingest the message.
- Hans suggested the recommendation be adjusted to include a grey zone to allow for time between the effective date of a published SOP and when it's actually operational.
- Hannah Galvin agreed with Hans.
- Steven Lane voiced concern about incentives in Row 4. ONC is attempting to incentivize the use of the Trusted Exchange Framework and Common Agreement (TEFCA) and if the recommendation is watered down, it may lose meaning.
 - Deven said the recommendation should be watered down. This recommendation could have the opposite effect. With the way this recommendation is written, flexibility in the information blocking rules may be taken away. In terms of individual access, there is no charge to accessing information using FHIR API endpoints. The Fees Exception in Information Blocking would be excluded for TEFCA participants.
 - Steven Eichner said public health agencies do not have a history of paying for data. He appreciates Deven's concerns.
- Row 4 will be revisited at the June 6 meeting. Row 5 in the document was left blank.
- Steven Lane reviewed Row 6 in the recommendations document.
 - The Task Force approved the Row 6 recommendations.
- Steven Lane reviewed Row 7 in the document.
 - The Task Force approved the Row 7 recommendations.
- Steven Lane reviewed Row 8 in the document.
 - Hannah said previous use cases have not required a third party in the flow of data. ONC should clarify what this looks like from an administrative burden perspective. The Task Force should ask for clarification on patient requested restrictions considering the 21st Century Cures Act.
 - Deven said there is little experience with HIPAA's right to request restrictions because it has been optional. The right to restrict can be honored in a nuanced way if the technology can support it and there is time to discuss and clarify with the patient. The patient may not understand all the downstream effects of withholding some of their health information.
 - The Task Force noted the standards may not be ready for a certification standard around use cases for this.
 - The Task Force agreed to move forward with the first bullet in Row 8.
- The Task Force moved forward with the second bullet in Row 8.
 - o Steven Eichner said the restrictions have not been set. It should be edited to say "deployed".
 - o Mohammad Jafari and Hannah agreed with the language change.
- The Task Force reviewed the third bullet in Row 8.
 - Deven noted HIPAA requires more than what is in this recommendation. This
 recommendation would be better suited as an item at the ONC Annual Report meeting.

PUBLIC COMMENT

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

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No questions or comments were received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the HTI-1 Proposed Rule Task Force. Please remember to tag "Everyone" when using Zoom chat.

Deven McGraw: The SOP for individual access today allows for some local decision making, as I recall.... Worry that even if an SOP is finalized, the required use of TEFCA for IAS if both parties are "participants" in some way could have negative consequences for IAS.

Eliel Oliveira: Deven, is there a need to recommend enforcement?

Deven McGraw: Rules aren't done yet, Eliel - the HITECH provisions went into effect a long time ago, but OCR won't enforce without rules, and I don't think they saw a technological way forward on this.

Eliel Oliveira:

Eliel Oliveira: Thanks everyone. I do need to jump on my next call. Great work!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Resources

<u>HTI-1 Proposed Rule Task Force 2023 Webpage</u> <u>HTI-1 Proposed Rule Task Force 2023 – May 30, 2023 Meeting Webpage</u> <u>HITAC Calendar Webpage</u>

Adjournment

The meeting adjourned at 12:00 PM.