

Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 1: Information Blocking

Meeting Notes | May 16, 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 16 was to review the Information Blocking (IB) Infeasibility Exception proposals on Existing Condition: Uncontrollable Events and New Condition: Third Party Seeking Modification Use. Group 1 also discussed the HTI-1 Task Force meeting update for the May 17th Health Information Technology Advisory Committee (HITAC) meeting.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events
11:00 AM	IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use
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

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
Adi Gundlapalli, CDC
Deven McGraw, Invitae Corporation
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Filipe (Fil) Southerland, Yardi Systems, Inc.

Members Not in Attendance

Sheryl Turney, Elevance Health



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 and charge detailed in the [May 16 meeting presentation materials](#).

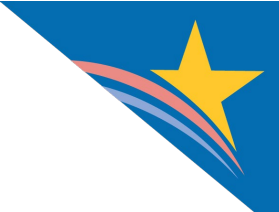
IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events

Daniel Healy, ONC, provided background on the Revised Existing Condition: Uncontrollable Events and Cassie Weaver, ONC, summarized the proposed changes, context, and benefits of revising the existing condition.

- The workgroup discussed and was supportive of the recommended language change.
- Hans Buitendijk recommended that ONC extend the 10-day infeasibility response timeline to start upon completion of the evaluation.
 - Deven partially disagreed with Hans's sentiment. She agreed 10 days may feel too short, but there should still be a deadline based on the time of the request. She feared items could be left on the backburner indefinitely if there is no deadline.
 - Michael said ONC has committed to actionable requests.
 - Steven Lane asked if 14 days would be better. Could the Task Force settle on a specific recommendation?
 - Michael said ONC is open to comments, however, there are legal considerations about what can be included in the Final Rule. ONC did not state in the NPRM that they are considering changing the 10-day timeline. The public needs to have notice of changes so they too can comment on them. As this was not part of the Proposed Rule changes; it is unlikely to change this time around.

IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use

Daniel Healy, ONC, recapped background on the New Condition: Third Party Seeking Modification Use. Cassie Weaver, ONC, reviewed the context and benefits of adding the New Condition: Third Party Seeking Modification Use. Michael Lipinski, ONC, provided a robust explanation of the infeasibility exception on the New Condition: Third Party Seeking Modification Use- Proposed Regulation Text.



Discussion

- Steven Lane asked if the change makes it easier for providers to use apps to write data into their EHR database.
 - Michael Lipinski noted ONC proposed that requests from a health care provider requesting use of EHI from an actor that is its business associate are excluded from this exception. Prior to this, third-party entities and business associates of the provider were similarly situated.
 - Steven Lane asked if the suggested change makes things better or worse for providers who want to use apps to write into their database.
 - Michael said it has not changed the situation for providers who wish to write to the record. ONC was careful when crafting this to not change that situation. This was also discussed in the 21st Century Cures Act Final Rule. The policy has not changed.
 - Cassie Weaver noted ONC issued a FAQ that further explains the business associate IB implications.
 - Michael Lipinski said the business associates are not exceptions to IB claims. The terms of business associate agreements could constitute an interference (and thus could be information blocking), subject to the facts and circumstances of each case.
- Steven Eichner noted there may be unintended consequences to the EHR's functionality due to data being written to the EHR.
 - Michael noted ONC acknowledged Steven's concern, but there is not a condition for that under feasibility – one could consider utilizing the Security or Health IT Performance exceptions.
 - Steven Eichner said it can be challenging to write to the record without unintended downstream effects.
- Deven McGraw said the definition of “healthcare provider” under Information Blocking extends beyond those who fall under HIPAA’s “healthcare provider” definition. There are data holders that are not always the provider’s business associates.
 - Michael said ONC must look at the big picture of investigation and enforcement, and their abilities in that space.
- Steven Lane clarified the proposed change does not increase the provider’s capacity to demand the ability to write data fields in an EHR. EHR vendors have various remaining exceptions that they may use to justify the refusal to allow provider-specified apps to write to medical records, whether the app was developed by the provider or purchased from an app vendor.
- Fil Southerland asked what happens when the EHR only allows read access to the data and no application programming interface (API) write access.
 - Michael said a lot of vendors have proprietary APIs. This would be infeasibility under circumstances that look at the resources EHRs have.
- Steven Eichner recommended ONC update certification requirements to support provider write-access using tools other than the primary EHR while minimizing risk to data security and EHR performance.

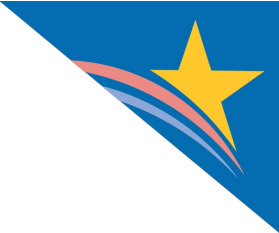
Planning for May 17th HITAC Meeting Task Force Update

Steven Lane reviewed the upcoming Task Force meetings. He reminded the Task Force to continue adding comments to the recommendations document.

PUBLIC COMMENT

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

QUESTIONS AND COMMENTS RECEIVED VERBALLY



- Melissa Soliz asked if there should be further language tweaks on enabling the use of data exchange to ensure the industry is aligned on how data is entered into the system.
 - Cassie Weaver noted ONC means the broadest definition of “use”. ONC is using “modification use” to differentiate this use and the HIPAA “use”. By saying “modification use”, ONC is referring to access exchange and use.
- Melissa also noted the exception does not address the burden when a new technology is adopted. It is burdensome to use infeasibility under the circumstances. Is there room in the Final Rule for infeasibility conditions when there are significant technology changes?
 - Michael Lipinski said ONC is always interested in comments, however there are legal limitations of what can be included in the Final Rule based on the contents of the Proposed Rule.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

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

Mike Berry (ONC): Link to the HTI-1 Proposed Rule Task Force presentation at tomorrow's HITAC meeting: https://www.healthit.gov/sites/default/files/facas/2023-05-17_HTI-1_Proposed_Rule%20Task_Force_Update.pdf

Melissa Soliz: For the public comment portion: is it permissible to suggest an additional infeasibility condition that was not included in the HTI-1 proposed rule, or is that beyond the scope of this webinar?

Sara Mcghee: To be considered, all comments (including comments organized using this document) must be submitted according to the instructions in the proposed rule. Electronic submissions are strongly encouraged and can be easily completed through the regulations.gov website (the proposed rule's docket is at: <https://www.regulations.gov/document/HHS-ONC-2023-0007-0001>). Look for the “Comment” button on the left.

Steven Lane: Anything can be shared during our public comment period, but the suggestion of an additional infeasibility condition would seem to warrant the submission of a formal written submission through the open public comment process. Members of the public are welcome to enter detailed comments here in Chat which makes them part of the public record and may give the task force an opportunity to discuss.

Steven Lane: Manner Exception Exhausted is scheduled for discussion on 5/23.

Steven Lane: Question: Does modification of EHI include the ability to add new instances of data elements (e.g., a new blood pressure entry, or medication) or only to modify data that has previously been entered, (e.g, correcting an erroneous entry or modifying a medication dosage for an existing med)?

Steven Lane: Question: Does TPSMU include a provider requesting that their Business Associate EHR allow a specified app to add data to and/or modify data already existing in the EHR?

Melissa Soliz: Question: Was limiting the new "third party seeking modification use" condition to "use" and not "use" and "exchange" intentional? "Use" is currently defined to mean "the ability for electronic health information, once accessed or exchanged, to be understood and acted upon." "Exchange" is the "the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks." The concern is whether it is available (or not) where the requestor is seeking to write new data to an actor's system (as opposed to deleting or changing existing EHI).

Rachel Nelson: We stated in the ONC Cures Act Final Rule that “acted upon” within the final “use” definition “encompasses the ability to read, write, modify, manipulate, or apply the information. . . .” (85 FR 25806).



Deven McGraw: @Mel Soliz - you raised this issue in another forum - but the definition of "provider" includes non-HIPAA covered providers. So there will be contractors to actor-providers who are not business associates. Suggests the exception should extend to nonBAs serving as vendors to providers.

Melissa Soliz: Question: Why is the TPSMU carve out to the exception limited to business associates? Does it not apply if the contractor is not a HIPAA business associate because the health care provider is not a HIPAA covered entity?

Deven McGraw: But having said that, am not sure why contractors need an exception. Why wouldn't the provider grant modification access to a contractor if that was within the scope of the agreement?

Deven McGraw: Under what circumstances would a contractor need an info blocking complaint in order to modify EHI over the objections of the provider?

Cassie Weaver: Relevant preamble, Mel: <https://www.federalregister.gov/d/2023-07229/p-1616>

Hannah K. Galvin: I echo Deven's question - I'm having trouble envisioning a situation in which a 3rd party would have access to create, modify or delete data in my system without a BAA. Do we have examples?

Deven McGraw: So should this exception be limited to certified EHR vendor actors?

Melissa Soliz: @Devin - thank you! I was typing that question as you were sending it. Example: non-HIPAA covered health care provider has a non-HIPAA business associate practice management vendor that wants to write data to the EHR. EHR vendor refuses and points to the new exception and says the carve out doesn't apply because the practice management vendor is not a business associate.

Cassie Weaver: To illustrate the purpose of this proposed question: <https://www.federalregister.gov/d/2023-07229/p-1614>

Melissa Soliz: @Cassie - thank you!

Hannah K. Galvin: That's helpful context - thanks, Michael.

Deven McGraw: I could see where a provider was trying to get its certified EHR vendor to allow another vendor to modify EHI (per the provider's request) and the certified EHR declined to do so...

Melissa Soliz: @Devin - Yes, that's it. The "business associate" issue only comes up when considering whether or not an actor can use this new infeasibility condition. That is, this condition is not available if the request is coming from a business associate of the provider. I don't understand why it wouldn't apply to another contractor that is not a business associate.

Daniel Healy (ONC): FAQ relating to BAAs: <https://www.healthit.gov/faq/do-information-blocking-regulations-require-actors-violate-existing-business-associate>

Rachel Nelson: Here is URL to the FAQ Cassie recently mentioned: <https://www.healthit.gov/faq/do-information-blocking-regulations-require-actors-violate-existing-business-associate>

Rachel Nelson: We state in HTI-1 preamble: As with every other condition in § 171.204(a), the proposed § 171.204(a)(3) third party modification use condition would stand alone. This means an actor's practice could meet it without needing to meet any other § 171.204(a) condition. It also means an actor's practice that fails to meet the § 171.204(a)(3) third party modification use condition could nevertheless satisfy another of the conditions, such as the infeasible under the circumstances condition (currently § 171.204(a)(3), proposed to be renumbered to § 171.204(a)(5)).

Melissa Soliz: @Accel Solution - sorry about! Thx for the clarification. Should I not use the chat either? Apologies - this is my first attending one of these.



Deven McGraw: Will do (adding to the document) - but likely will do so when I catch up with my homework after the call ;)

Melissa Soliz: On language tweaks: wouldn't changing it to "use or exchange" also be important to clarify that it covers how the data is written? I think one of @Michael's comments during the discussion was whether the data was being written via API, certified API, or other means.

Fil Southerland: +1 to Ike's comments regarding scoping write access to EHRs. It seems that we're trying to back into write access via modification requirements when the question of modification may be more directly addressed via EHR write requirements. Full write of EHI is a significant burden for EHRs, but a more limited scope aligned to US Core may be more appropriate.

Katherine Lusk: @Hans - Do you think the general public understands that technically it is difficult to get information to them in 10 day?

Hans Buitendijk: @Katherine - complexity is inherently a challenge to assess and clarify where the specific parties are best positioned to understand that, not necessarily the general public who may not have the context and depth on what is actually needed to make it happen. These are requests by specific parties for specific capabilities in their context.

Melissa Soliz: Question: has the group considered extending the carve out to the new modification exception to other kinds of actors (in addition to providers)? For example: HIN/HIEs may have platforms supported by health IT developers actors who are placed in situations similar to providers where the developer actor denies a request to write data to the platform because the writing is being done by another technology vendor acting on behalf of the HIN/HIE.

Rachel Nelson: 171.204(a)(1): Uncontrollable events. The actor cannot fulfill the request for access, exchange, or use of electronic health information due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.

Rachel Nelson: What I pasted above is the reg text in place for this condition under Infeasibility Exception today.

Melissa Soliz: @Rachel - on this notice question that is being discussed, is there any existing guidance from ONC on what constitutes "notice"? It seems to go with the discussion that is being had with the hurricane example and giving notice.

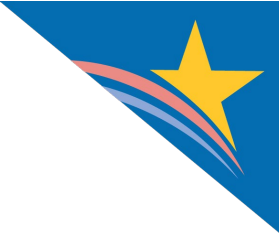
Hans Buitendijk: @Ike - Could we use HIT more broadly rather than focusing on EHRs only? I understand that the option listed is one reason, but EHRs may not be the primary HIT of interest that has relevant data where the same challenges may arise. Certain writes can go directly into an HIT, while others need to remain "on the side" until reconciliation or just stay on the side. Yet they are still writes that are more or less feasible based on context.

Cassie Weaver: <https://www.federalregister.gov/d/2023-07229/p-1612>

Rachel Nelson: To submit a formal comment on the HTI-1 proposed rule, you can click the "submit a formal comment" button at the top of the rule's page on Federal Register website: <https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>

Deven McGraw: I think we can make that comment - we just shouldn't expect that ONC can act on it in this final rule. Doesn't mean they couldn't take it under consideration for a future rulemaking

Cassie Weaver: for attorneys, it's called "logical outgrowth"



Mark Savage: This member of the public would like to solve the problem directly and require certified write access FHIR APIs in place for use and exchange for so many important use cases (PGHD, PRO, SDOH, remote monitoring, device data). Not including in this NPRM means another round of rulemaking and adds more years to the delay.

Deven McGraw: And arguably if we put it in the parking lot for a future rule, doesn't that make it more likely it will end up in a future proposed rule.

Deven McGraw: We should prioritize comments on the proposed rule text - but could we not have a section on recommended future rulemaking?

Hans Buitendijk: +1 Deven

Michael Lipinski: Yes to Deven's statements

Melissa Soliz: Thanks all for having this open to public comment!

Deven McGraw: These meetings are terrific and very informative. Thanks to staff, co-chairs, fellow members, and our public participants for the substantive dialogue.

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 16, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

Adjournment

The meeting adjourned at 12:00 PM.