Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 2: ONC Health IT Certification Updates- New and Revised Certification Criteria

Meeting Notes | May 24, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Group 2 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 24 was to discuss Patient Requested Restrictions Certification Criteria and Data Segmentation for Privacy and Consent. A robust discussion followed the criteria and data segmentation agenda items.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Patient Requested Restrictions Certification Criteria
11:10 AM	Data Segmentation for Privacy and Consent
11:20 AM	Discussion
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 Eichner, Texas Department of State Health Services, Co-Chair, Group 2 Lead
Steven Lane, Health Gorilla, Co-Chair
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Anna McCollister, Individual
Aaron Miri, Baptist Health
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Fillipe (Fil) Southerland, Yardi Systems, Inc
Sheryl Turney, Elevance Health

Members Not in Attendance

Anna McCollister, Individual
Aaron Miri, Baptist Health
Naresh Sundar Rajan, CyncHealth

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Sara McGhee, ONC
Elisabeth Myers, 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 2 attendees. Group 2 lead, Steven Eichner, reviewed the meeting agenda and charge detailed in the May 24 meeting presentation materials.

Patient Requested Restrictions Certification Criteria

Elisabeth Myers, ONC, reviewed the new Criteria Proposal and its Benefits. The Proposal takes a standards agnostic approach, and ONC seeks comment on whether that is the best method. ONC also seeks comments on the certification criteria. In the Proposal, it would reference the Health Level 7 (HL7) Clinical Document Architecture (CDA) Data Segmentation for Privacy (DS4P) Implementation Guide (IG) and the HL7 Fast Healthcare Interoperability Resources (FHIR) DS4P IG. Elisabeth further explained ONC requests information on if there are modifications or restrictions to consider when developing privacy workflows under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Data Segmentation for Privacy and Consent

Mohammad Jafari provided recommendations for privacy and consent. There is a tight coupling between patient preferences and data segmentation. He added there is a need for a cohesive view of granular patient preferences and data segmentation in one system. Standard labels, such as confidentiality labels, for example, are key to providing language that expresses patient preferences and provides agreement on the meaning of the labels. Mohammad noted there is sufficient implementation guidance for recording labels in FHIR, CDA, and version 2 (v2); however, there is inconsistency in assigning the labels.

Discussion

- Jim Jirjis noted not all patients are proficient in the health IT space. He voiced concerns over patients accidentally sharing information they did not want to. There may be unintended consequences.
    - Elisabeth Myers agreed. Within United States Core Data for Interoperability (USCDI), there could be information that is sensitive and that the patient does not want to be shared. ONC understands this Proposal will not solve the whole problem, but it can give a good start. Existing requirements within HIPAA will not be changing.
- Hans Buitendijk agreed with Beth that this challenge is only growing. The Task Force should focus on

recommendations that are incremental. This issue is extremely large and complicated, but steps should be taken towards solving this issue.

- Steven Eichner said ONC should ensure the patient's requests are honored. Providers need to honor the patient's requests, and the technology needs to support that. He recommended the workflow include a section where patients can follow up on their requests to ensure their needs are being met.
- Hans agreed with Mohammad that there is an opportunity to align key vocabulary that can be interpreted the same by each party. He agreed there are data elements that need to be exchanged because they are essential to maintain. Confidential and sensitive labels may change as patient preferences change.
    - Mohammad said if a patient changes their mind or jurisdictional change happens, it reflects changes in policy and may not apply to the recipient jurisdiction. Labels give systems a tool to share this information, and the policy can still be applied by general access control systems.
    - Hans added the labels will need to note that the label was applied on a specific date in the event a patient's preferences change.
    - Mohammad agreed and said there is an IG that outlines the policy around labels.
- Sheryl Turney said a coding system may be needed to earmark these label categories. She does not know enough about the labels in Fast Healthcare Interoperability Resources (FHIR) and how they can be utilized. At a minimum, there needs to be patient education on how the labeling system works. The Task Force should also comment on potential challenges with variances between states. There is a risk with sharing information across different jurisdictions.
- Hans said there is also a challenge for patients seeing multiple providers. What happens if a patient changes their preference with one provider? How does it change across the board?
    - Mohammad said if the FHIR Consent resource is used in a consistent way, that change can be reflected. Consent management systems can help patients articulate their preferences.
- Deven McGraw said state consent laws are complicated. Federal law has some slowdown obligations. Additional context is needed to understand a use case that allows ONC to build in capacity to leverage technology and comply with those obligations.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

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. Meeting materials can be found at: https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2-3

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

Jim Jirjis: Does this mean it would be restricted from sharing with ANYONE, even all of the permitted uses? And would it be forever, or is there an implied ability for the patient to reverse it?

Steven Lane: These standards have been around and evolving for years. They are now quite mature and ready to be named in regulation. Why add years to our wait for this functionality by delaying the requirement to use standards for one or more additional rule making cycles??

Hans Buitendijk: Establishing restrictions is really about consent management, and it is easy to "wrong" without common guidance and an infrastructure to actually enable to manage this as the data is being shared

and as restrictions are added/removed over time after/as data has been shared. Thus vey concerned that this Proposal will not achieve its goals.

Hans Buitendijk: Note the alternatives do not include all the paths data flows.

Steven Lane: Agree Hans. The alternatives, as presented, only suggest certain options. The ideal next step may be a selection of characteristics from various alternates as presented.

Jim Jirjis: I have questions about feasibility. For example, if a patient wished to hide their HIV status, they may go in and restrict that HIV ELISA test, but not necessarily a PCR or western blot. Additionally, a provider may indicate in their notes that the patient is HIV position and it also may be in the problem list, etc, in various places in the record (all within USCDI). So if the patient means to restrict sharing that they are HIV positive, this seems infeasible and could falsely create expectation that a provider would don't share anything about HIV status. The state of the data does not allow for this to be feasible or reasonable at this time

Hans Buitendijk: Suggest to focus on a well defined set of flags and data characteristics against which consent rules can be expressed. That is a critical step so data that needs a flag beyond already exiting characteristics data attributes are interpreted the same by everybody, by whatever means the data is shared.

Hans Buitendijk: We then also need to focus on the key question how restrictions can be shared so patients need not express them and manage them for every location where that data may actually exist, which is not just at the source.

Vik Sachdev: Tags become static and require either they be applied during load or require full scan be done on data continuously to keep up with user settings

Vik Sachdev: suggest looking at FHIR Path

Hans Buitendijk: Data is shared using v2, C-CDA, FHIR, SCRIPT, and proprietary.

Steven (Ike) Eichner: Patient education about the impact of non-disclosing information is also critical.

Steven Lane: The complexity of all of the presented options make it tempting to keep this incremental step very limited. We should not miss this opportunity to make meaningful progress to support granular patient privacy controls.

Steven (Ike) Eichner: And, building on HANs' comment, relevant data may be stored in a wide range of fields within each of those sharing mechanisms.

Jim Jirjis: @Ike. Agree. Concerned that some patients will restrict a large part of the record and we could end up in situations where caregivers cannot provide safe care

Steven Lane: Agree w/ Hans that we should not limit the applicability of this requirement by data format or transport mechanism.

Deven Mcgraw: Today the patients' right to request a restriction under HIPAA is only required to be honored if the patient pays in fill out of pocket and wants to restrict disclosures to health plans. All other requests for restrictions under HIPAA are voluntary for covered entities and business associates to honor. So for entities who want to grant more restrictions, having some functionality to do so is helpful. I believe entities could also grant restrictions in this voluntary category with caveats regarding what the restrictions could cover or accomplish (ie. Can't control for data inferences….)

Hans Buitendijk: Focusing on targeted data within USCDI, and a target set of flags in combination with the already available data to assert rules against is essential to establish a foundation we can the build on and scale. Referencing either of the guides generally would create a high risk of widely varying interpretations

and implementations that will create barriers to scaling, and will not manage the data that has already been shared.

Hans Buitendijk: +1 to Steven to keep this incremental step very focused to create that foundation. Also, should apply the learnings of the LEAP project that Mohammad can speak to.

Steven Lane: @Jim - This will be challenging to implement, but it is a challenge that our industry must take on now and over these next couple of years.

Jim Jirjis: It is easy to rally behind the notion of patient control of information, but we could also then as a result have blinders on as to the unintended consequences with patient expectation or safety of care.

Steven Lane: The DS4P standard allow data to be visible to decision support but hidden from individuals, so that providers can be alerted to an actionable insight and then break the glass to access it.

Jim Jirjis: @Steven, agree but just caution that we do not move to fast without weighing risks

Steven Lane: Dr. Jafari can comment on this capability.

Luis Palacios: Grant old records are grandfathered and excempt. but anything forward from 2025 is covered. The context of olf files is not possible without AI as human review of records is impossible.

Hans Buitendijk: DS4P works for CDA but not FHIR, v2 or others. Security Labels work on FHIR, not others. The underlying terminology can work across more, but is "too flexible" and can still easily lead to divergence.

Deven Mcgraw: Very important point on the limits of the hipaa right to restrict - but often the consent requirements in state law are more definitive.

Elisabeth Myers: Yes, and we note that in the rule as well. Our approach is aiming to stay within a swimlane that allows users to implement the tool within the context of the laws applicable to them

Hans Buitendijk: @Kikelomo - That certainly can be part of it. E.g., certain demographic data on a patient could be field level masking. That works well within an organization, but how can that be conveyed to the next party you share it with? That's where flags/tags may need to come in. While for other attributes one can assert it based on values, e.g., diagnosis codes/groupings, test codes and/or results, etc. We all need to understand how that is done consistently to ensure we collectively can manage across highly diverse HIT.

Vik Sachdev: Really like using FHIR Consent and Audit

Hans Buitendijk: Data we exchange should be data that is as stable as possible, not subject to policy changes. Internal tagging is done to help more easily identify data subject to the rules, but as much as possible one could derive it "all" from that the real data already there. Only then, as that is shared, another party can always assess in context of the then current rules (privacy by jurisdictions and consent by patients) how to honor those rules.

Hans Buitendijk: Agreed that the foundational standards in HL7 can carry flags, but a clear focus on which focus should be exchanges, which ones are better used internally only, and ensure the actual source data that rules are applied to are well understood does not have within HL7 clear alignment. And that is only within HL7.

Hans Buitendijk: HL7 v2 ARV (2.9) could handle sensitivity labels.

Steven (Ike) Eichner: Without flow-down of changes in patient disclosure permissions and without the patient having access to a record of disclosures, a patient's data may be disclosed without their authorization or

knowledge. With flow-down, if a patient doesn't know to whom their data was previously disclosed, there may be some opportunity for patients' requests to be transmitted and followed.

Sheryl Turney: I agree with Steven's comment here. We need education for the patient and also some recommendation that communicates the flow down obligations.

Steven Lane: Even though the laws do not flow down, the fact that a restriction has been applied should be available to follow the data.

Deven Mcgraw: Oops - meant to reply to everyone. State law restrictions don't tend to flow down. Part 2 obligations do.

Deven Mcgraw: Restrictions requested by patients under hipaa generally would not flow down

Deven Mcgraw: +1 to Sheryl.

Hans Buitendijk: @Deven - They don't flow down, but the then current state and implications can change. That means that, similar to patient consent rules, they can change and need to be interpreted not necessarily relative to time and source of origin. So we need a mechanism enables data holders to have all the rules accessible at the time they are asked to share, or need to push data.

Sheryl Turney: Also, restricting data is complex based on my knowledge of what payers have to do with sensitive services.

Deven Mcgraw: Agree, Hans - and there are many providers who misunderstand what those state law obligations are (understandable - the laws can be hard to find and digest; many are not robustly enforced so there is little understanding among a range of stakeholders about them).

Steven Lane: Thank you @ Sheryl. It is important to consider various data holders, recipients and users as we develop our recommendations.

Steven (Ike) Eichner: +1 Hans on data flow and constraints across providers. Made more complicated if the patient does not have access to a list/links of to whom a provider has disclosed their information.

Hans Buitendijk: As patient consent/restriction rules need to be applied in combination with privacy rules, a common infrastructure/set of standards is essential to consistently assess whether to share data or not.

Hans Buitendijk: Having one set of well defined privacy rules across jurisdictions that are computable, expressed in FHIR and maintained would be a great initiative to focus on.

Steven Lane: Agree, Hans. Please articulate this in recommendations.

Mark Savage: +1 Deven McGraw's verbal comment. Ensuring that the individual understands what is and is not occurring is critical to the overarching need to preserve the trust fabric/framework.

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 24, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 11:59 AM.