Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 3: ONC Health IT Certification Program Updates – Insights Conditions, Standards Updates, and RFIs

Meeting Notes | May 4, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Group 3 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 4 was to recap the Task Force Charge and timeline, review the United States Core for Data Interoperability (USCDI) version 3 (v3) Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR) US Core Revisions, and walk through standardized API updates.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge and Timeline Update
10:40 AM	USCDI v3 C-CDA, and FHIR US Core Revisions / Standardized API Updates
11:50 AM	Public Comment
12:00 PM	Adjourn

Call to Order

Seth Pazinski, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:32 AM.

Roll Call

Members in Attendance

Steven Eichner, Texas Department of State Health Services, Co-Chair
Steven Lane, Health Gorilla, Co-Chair
Hung Luu, Group 3 Lead
Hans Buitendijk, Oracle Health
Clem McDonald, National Library of Medicine
Naresh Sundar Rajan, CyncHealth
Filipe (Fil) Southerland, Yardi Systems, Inc.

Members Not in Attendance

Elaine Johanson, FDA
Meg Marshall, Department of Veteran Affairs (VA)

ONC Staff

Seth Pazinski, Acting Designated Federal Officer, ONC
Scott Bohon, ONC
Kyle Cobb, ONC
Keith Carlson, ONC
Dustin Charles, ONC
Carmela Couderc, ONC
Sara McGhee, ONC
Michael Wittie, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge and Timeline Update

Steven Eichner and Steven Lane welcomed Group 3 attendees to the HTI-1 Proposed Rule Task Force (Task Force) meeting. Group 3 lead, Hung Luu, reviewed the agenda and charge outlined in the May 4 meeting presentation materials.

USCDI v3, C-CDA, and FHIR US Core Revisions / Standardized API Updates

Kyle Cobb, ONC, provided background on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing rules. Carmela Couderc, ONC, recapped the proposed Certification Standards and Functionality Updates. Then, Carmela reviewed USCDI v3 and C-CDA Companion Guide updates, as well as Health Level 7 (HL7) FHIR US Core updates. Lastly, Kyle reviewed the Revised Criterion for Standardized Application Programming Interfaces (APIs), the Substitutable Medical Applications Reusable Technologies (SMART) v2 Guide for New and Revised Requirements, Patient Authorization Revocation, Scope Mapping, and FHIR Endpoint Specifics.

Discussion:

- Hans Buitendijk stated progressing to USCDI v3 makes sense. The Task Force should just be aware that there will be practical experiences that demonstrate gaps. The larger challenge is that USCDI is expanding to cover full electronic health information (EHI). He suggested reviewing USCDI health information technology (HIT) criteria with the broader Health Information Technology Advisory Committee (HITAC).
- Fil Southerland said the need to conform to the entire USCDI data set is a barrier in the specialty electronic health record (EHR) community. Specifically, there is very little HIT uptake within the pediatric sector, resulting in a patient access issue.
    - Since there is limited certified HIT in the pediatric sector, he noted there is fragmented interoperability and patient access. It is a heavy lift to encompass all the data, especially if it is not applicable to the client base.
- Hans also noted in the EHR community that there has been discussion on data being managed by the system rather than requiring data that is not otherwise useful. There is consensus in the EHR community that systems should not have to support data elements when users do not need them.
- Steven Eichner noted he is concerned about certifying only a limited part of USCDI. Public health reporting will still need certification, and that can get complicated.
- Fil said he supported Hans's notion of specialty EHRs displaying only the information relevant to the

user community. He also noted he does not want ONC to miss the opportunity of focusing on whole person health. It is important to find a way to solve this and work towards health equity.

- Hung Luu said that the "red line in the sand" for him is transmission. Healthcare is an ecosystem, and data flows from organization to organization. The information that is being exchanged must be complete and accurate without loss of meaning. A piecemeal approach to certification may create a big loophole that undermines interoperability efforts.
    - Hans agreed. Sometimes at the hospital level, there may be a variety of systems being used. To be consistent with interoperability, there cannot be a "one size fits all" approach to this issue. There have been discussions regarding ONC's and CMS's approaches to certifications. As the industry advances and certification standards point to newer versions of USCDI, ONC should consider how to support specialty EHRs and other HIT products in achieving and maintaining certification. ONC could consider allowing certified products to receive, maintain, display, and exchange all USCDI data elements while only managing the data elements relevant to their users. USCDI has a growing library, and the industry needs it. However, the focus should be on how to enhance the granularity and certify only what is relevant to that organization.
- Fil added it is important the group establishes what the population for USCDI exchange is. Is it a formal EHR, or are we looking to exchange with community-based organizations?
    - Steven Eichner noted the current focus of USCDI is on what is being transmitted, not who it is being transmitted to.
- Steven Lane asked the ONC team if vendors, who are certified to current versions, are looking to update to newer ones through Standards Version Advancement Process (SVAP)? Is the industry shifting that way?
    - Kyle Cobb said ONC has not been doing this for very long, so the uptake has been slow. However, ONC has seen more advancement and willingness from developers to advance to later standards through SVAP. It has been a slow start, but it is picking up.
- Hans said he is a bit confused regarding the timeline of standards. What is the general approach that is intended to move forward on aligning code systems?
    - Carmela said code system version updates are a standard that customers would ask for. Code systems update on different cycles; Logical Observation Identifiers Names and Codes (LOINC) codes come out at a different time than Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), for example. ONC was not planning on providing that information. She noted ONC currently cannot speak on anything outside what is proposed.

PUBLIC COMMENT

Seth Pazinski opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

Ian Sefferman thanked everyone on the call for their hard work. He noted his perspective as a developer is based on patient advocacy. The inclusion of implementation guides that aid in matching vocabulary between systems will be important. The JASON bundle is helpful from a developer perspective but may not be for others.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: Welcome members of the public! Feel free to utilize the Chat function to contribute to our task force discussion as well as the time set aside for verbal public comments 10 minutes before the end of our meeting.

Steven Lane: Today's meeting materials are available at https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-3-0

Hans Buitendijk: The proposed approach continues to require certified HIT to support all of USCDI through C-CDA and FHIR US Core. For specialty EHRs and other HIT that could benefit from certification forces support of more data than necessary. Other programs could not easily reference CHIT to the level of granularity relevant. Suggest that CHIT only needs to be certified to the data it manages discretely (collection by UI and/or ingested from documents/transactions for discrete use), while when received through documents it can still view/display other data included.

Fil Southerland: +1 Hans

Mark Savage: @Hans, I'm wondering if there are other reasons (besides specialty use) that may warrant all being able to reference full USCDI. What immediately comes to mind is the CMS transition to dQMs which will reference a variety of data elements in the process of automatically calculating increasingly robust dQMs.

Hans Buitendijk: @Mark: The question is for eCQMs and dQMs whether the measures would be applicable in those situations. If relevant, thus need to be managed for that context to be managed discretely, it would then be within scope.

Steven Lane: It is very reassuring to see how deeply ONC has gone into the evolving technical standards and identified specific opportunities to improve the privacy, security, and utility of data exchange.

Steven Lane: I think that Hans' point is the same one that we have discussed repeatedly in the past, that the inclusion of data elements in USCDI does not require users to collect these data, nor should it require HIT to fully manage data that is not applicable to users of that HIT. I think that the proposal, to allow all USCDI data to be received and viewed, without the need to provide full data management tools for inapplicable data classes/elements, strikes a reasonable balance IF we want to be able to extend certification to specialty EHRs and other HIT products.

Steven Lane: Respecting patient requests for revocation within 1 hour would be a huge step forward for patient control over their health data and their confidence in utilizing HIT.

Ian Sefferman: For public comment: while a worthy goal, the inconsistency in endpoint standards is actually _less_ burdensome for developers (such as ourselves at Goodbill) than the burden of *getting the credentials* for those endpoints. it'd be good to address BOTH concerns.

Mark Savage: @Hans, @Steven, Another use case that might help consideration is dynamic shared care plans/planning among the individual and different care providers providing different services (e.g. multiple chronic conditions).

Steven Lane: Thank you Kyle and Carmela for the clear and comprehensive presentations.

Fil Southerland: @steven - have reasons been identified in the past that we'd not want to extend the cert program to specialty EHRs? From my perspective, ONC needs to focus more on access equity for patients under the care of providers in these specialty sectors that have little CHIT uptake.

Steven Lane: @Fil - We have time to discuss. I am of the opinion that we should encourage HIT certification to as broad a group of products as possible.

Steven Lane: Not only full function EHRs for primary care and hospitals.

Sarah Irey: The current program makes it difficult for specialty EHRs to certify and this then limits the ability for specific providers to participate in quality programs - such as MIPS - or they have to take a payment penalty.

Steven Lane: Certification of specialty EHRs and other HIT products should improve interoperability and care coordination across the board.

Steven Lane: We are likely to have time for additional public comment. I STRONGLY encourage members of the public who have provided input in Chat take the opportunity to voice your thoughts to the task force.

Steven Lane: Members of the public who would like to provide verbal public comment are encouraged to use the hand raising feature to get into queue.

Hans Buitendijk: @Ike: Completely agreed.

Hans Buitendijk: And I don't think those are contradictory. Where you provide immunizations, thus need to report in it, one has to discretely support those data. But if one does not support immunizations, why should that HIT support all the elements critical to that, but at most a subset. It comes down to what data is relevant at the discrete level to perform all the functions.

Seth Pazinski: This ONC blog addresses some of the earlier discussion regarding scope of ONC standards. https://www.healthit.gov/buzz-blog/interoperability/e-pluribus-unum

Mark Savage: Re TF's discussion of USCDI, may help to look at slide 21, which shows the eight HIT modules that reference USCDI. Seems this also manifests balance, and the balance being discussed to have a national set of core data for interoperability that can be used across priority use cases as needed, rather than differing subsets. Hung Luu's comment about a big loophole in interoperability resonates with me.

Hans Buitendijk: Acknowledging Seth's reference that USCDI supports not only certification, thus the pace of expansion desirable for one program may not be the same as for another. However, for certification it is not necessarily the pace, but the coarsness.

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 4, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 11:55 AM.