

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 10, 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 10 was to review the regulatory approach for certification criteria and plan for the May 17th Health Information Technology Advisory Committee (HITAC) Task Force update. A robust discussion followed the review of the new regulatory approach for certification criteria.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	New Regulatory Approach for Certification Criteria (“Edition-less”)
11:00 AM	Discussion
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


Wendy Noboa, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:33 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
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Anna McCollister, Individual
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CynHealth
Filipe Southerland, Yardi Systems, Inc

Members Not in Attendance



Medell Briggs-Malonson, UCLA Health
Aaron Miri, Baptist Health
Sheryl Turney, Elevance Health

ONC Staff

Wendy Noboa, Acting Designated Federal Officer, ONC
Michael Lipinski, ONC
Sara McGhee, ONC
Kate Tipping, ONC
Maddie Zeng, 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 10 meeting presentation materials](#).

New Regulatory Approach for Certification Criteria (“Edition-less”)

Michael Lipinski, ONC, noted ONC is discontinuing year-themed “editions” for certifications and then reviewed applicability and expiration timelines for certification criteria and standards, as well as compliance criteria.

Discussion:

- Steven Lane said it would be nice to have a graphic that clarifies where the standards version advancement process (SVAP) fits into this approach.
 - Michael Lipinski thanked Steven for the feedback and noted he would take it back to ONC.
- Hans Buitendijk clarified there may be overlapping timelines with other related standards initiatives, such as the United States Core for Data Interoperability (USCDI) updates. How will this be managed?
 - Michael requested Hans indicate this concern in the recommendations document. He appreciated raising this flag. ONC will want to hear about the overlapping timeline concern.
 - Steven Eichner noted the overlapping timelines may be an issue from a communications standpoint as well.
- Hans asked if the competing USCDI and certification timelines are because ONC is transitioning the regulatory approach or if this will be an ongoing issue.
 - Michael said it is policy driven by what ONC wants to see. The rule is a proposal, and ONC is looking for public comment.
- Fil Southerland asked what the enforcement monitoring mechanism is for tracking vendor contracts. Is that public information?
 - Michael said that would be a good point for comment. He was not sure if ONC was looking to monitor that.
- Steven Eichner noted there is significant time between a standard being developed and it being implemented. He was wondering where there may be opportunities to accelerate adoption without jeopardizing the standards development and implementation process.
 - Michael said that approach seems viable but will circle back with him.
 - Hans noted having a framework that is flexible would be beneficial.
 - Fil flagged this will continue to exacerbate the burden on specialty EHRs to keep information



- they are not the source for.
- Steven Lane asked how deep the Task Force is digging into the recommendations for updated certification criteria in the NPRM. Is this already being addressed in one of the workgroups? Should the Task Force be providing comments on it?
 - Wendy Noboa said she would take it back and get clarification.
 - Steven Eichner asked how the two sections of the rule intersect with each other.
 - Michael anticipates the certification criteria will be reviewed in depth with the Task Force.
 - Anna McCollister said it is challenging and time-consuming to implement new rules. She emphasized how burdensome reading through the proposed rule is for the average patient. ONC and the Task Force need to find ways to get input from patients without burdening them with reading the entirety of the 500-page proposed rule.
 - Michael noted cost benefits are not always quantifiable. ONC tries to weigh the cost, which is typically symbolic of burden. They try to be mindful of that when putting together their timelines.
 - Anna reiterated the rule is 500 pages and will have a significant impact on patients, and it is significantly easier to read if people work in the industry. What would be the best way to zero in on the elements that matter most to individual patients? It is a substantial burden on patients to read through and assess.
 - Michael said he was happy to talk with Anna directly about this issue.
 - Hans agreed with Anna's comments. It is hard because of the variety of perspectives to understand which data is most relevant.
 - Anna noted if ONC and the Task Force are serious about getting input from the intended beneficiaries, they will need to figure out better ways than reading through a 500-page proposal.
 - Steven Lane said HITAC has asked ONC for clarity on what each Task Force should focus on. Asking ONC if they have some ability to organize the proposed rule from the patient's perspective may be beneficial.
 - Steven Eichner agreed. There may be some aspects of the rule that may pertain to some patients more than others.

Planning for May 17th HITAC Meeting Task Force Update

Steven Lane encouraged the Task Force to continue adding comments in the recommendations document. He asked the group if there were any items the Task Force should highlight with the full HITAC. Steven Eichner reviewed the ONC recommendations document.

Discussion:

- Hans said the Task Force could give HITAC a heads-up on the competing proposed rule and USCDI timelines.
 - Steven Lane asked Hans to craft language on that to bring to the HITAC.
- Anna asked if it were possible for some ONC support staff to take comments from Task Force members and incorporate them into the spreadsheet to reduce the burden on Task Force members.
 - Steven Lane agreed she had a good point and took it as a suggestion for the co-chairs to discuss with ONC.
- Steven Lane suggested Fil adjust the language in the recommendations spreadsheet to include "ONC should..." or "Recommend ONC...".
 - Michael suggested the Task Force be as specific as possible in the recommendations document.

PUBLIC COMMENT



Wendy Noboa opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

Mark Savage said the USCDI Task Force ran into similar timeline issues two years ago. It is important to track the competing timelines and be flexible as the regulations progress.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: ONC has received feedback regarding the confusion generated by the year themed editions for many years.

Steven Lane: How will this proposed change impact the function of the existing SVAP program?

Hans Buitendijk: Would this yield HTI-n.m releases to distinguish small from large?

Hans Buitendijk: On slide 17 though, hypothetical, if the FR is Jan, then it is 35 months, right?

Hans Buitendijk: So slide 19 would imply that if USCDI v3 is in FR on November 1, 2023, then we need to be on USCDI for (g)(10) 14 months later?

Wendy Noboa: Just a friendly reminder, all meeting materials for today are available on HealthIT.gov: <https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2-1>

Hans Buitendijk: For HITAC comment consideration (I'll put in spreadsheet) the coordination of multiple tracks, varying timelines, total workload for all parties involved, etc. makes it challenging. Closer alignment of timelines making change more predictable is essential.

Steven Lane: +1 Hans. Thank you for drafting proposed language for a TF recommendation.

Mark Savage: I'm reminded of the USCDI TF's and HITAC's recommendations two years ago around USCDI v2 to move more strategically and less incrementally.

Fil Southerland: Agree Hans.

Mark Savage: I don't think I can talk now.

Steven Lane: Members of the public with comments they would like to share verbally should feel free to raise their hands now so we can have a sense of the volume of comments.

Sara Mcghee: For your awareness ONC put together a Public Comment Template and word version on the HTI-1 page: <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>

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 10, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)



Adjournment

The meeting adjourned at 12:01 PM.