

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 | April 26, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force Group 2 session on April 26 was to review the HTI-1 Proposed Rule Task Force Charge, recap the Task Force Topics Worksheet, and walk through the Decision Support Interventions (DSI) and Predictive Models proposed revisions, scope, and requirements.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Task Force Topics Worksheet
11:05 AM	Decision Support Interventions (DSI) and Predictive Models
11:55 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
Steven Lane, Health Gorilla, Co-Chair
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Aaron Miri, Baptist Health
Kikelomo Oshunkentan, Pegasystems
Fillipe Southerland, Yardi Systems, Inc.
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health



Members Not in Attendance

Anna McCollister, Individual

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Dustin Charles, ONC
Jordan Everson, ONC
Kathryn Marchesini, ONC
Sara McGhee, ONC
Jeffery Smith, ONC
Michael Wittie, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge

Steven Eichner welcomed the attendees to the Task Force meeting and reviewed the April 26 agenda. He recapped the overarching HTI-1 Proposed Rule Task Force Charge. Steven Lane explained he will be facilitating the Tuesday Task Force meetings, Steven Eichner will be facilitating the Wednesday Task Force meetings, and Hung Luu will be facilitating the Thursday Task Force meetings. Task Force members are encouraged to contact the co-chairs if they would like to invite subject matter experts to the meetings.

Task Force Topics Worksheet

Steven Eichner and Sara McGhee reviewed the Task Force Topics Worksheets. Steven Eichner oriented the members to the various tabs, specifically group 2's. He provided the members with guidance on how to input information into the group 2 tab and explained that members have access to view all tabs. He also reviewed the schedule tab.

DSI and Predictive Models

Jeffery Smith recapped ONC's Disclaimer and Public Comment Guidance detailed within the [presentation slides](#). Jeffery reviewed information on Decision Support and Certified Health IT, Scope of Certification and Decision Support Criterion, Proposed New Requirements, Related Request for Comment, Proposed Predictive DSI Attestation, Proposed Scope of Covered Technologies, and discussed which DSIs would need to adhere to ONC proposed requirements. He then moved into a recap of source attributes. More information on source attributes will be reviewed on the May 3 call.

Discussion:

- Steven Lane invited Task Force members to pick up the conversation from April 25.
 - Hans Buitendijk asked more about the context of health information technology (HIT) which is not considered a base electronic health record (EHR). If there is a patient-focused app that has DSI capabilities and an EHR interacts with it, that may impact the Task Force's recommendations.
 - Jeffery Smith said the context may become clearer as the presentation goes along. However, if the patient-facing app is not enabled by a health IT module (such as an EHR) and it has DSI capabilities, it would not be required to adhere to ONC transparency requirements.



- Steven Lane noted there will be a real opportunity for the market to pick up these requirements.
 - Jim Jirjis noted the United States Food and Drug Administration (FDA) has also released a guidance document that has broader guidance for apps. In the FDA's document, patient-facing apps would be considered devices that must be regulated.
- During the DSI and Predictive Models presentation, Hans asked theoretically if a health IT module is "calling" another module to provide the DSI, the module being "called" does not need to have an ONC certification?
 - Jeffery said yes.
- Jeffery further explained the current expectation is that ONC does not require other parties to require scope attributes. If a health IT module works with another party for clinical decision support, the health IT developer is expected to work with that other party to get the citation. If it is not there, it needs to be indicated.
- Medell Briggs-Malonson noted that if a certified electronic health record (EHR) interfaces with a third party and no citations come forward, it may be a loophole. There needs to be accountability, along with transparency, in the Proposed Rule.
 - Jim noted the current workflows may not cover third parties using DSI. This Proposed Rule ensures there is a spot for it in the workflow.
 - Medell agreed and said there should be a seamless connection so users have confidence that the technology has been vetted.
- Steven Eichner reminded participants that verbal comments cannot be considered by ONC. He encouraged Task Force members to put their comments into writing inside the provided homework spreadsheet.
- Hans asked more about the scope and definition for DSI.
 - Jeffery noted there is a slide that details more about the scope. He further explained if the intended use of clinical decision support is achieved by a machine but was previously achieved by a human, it would be considered predictive DSI and meet the definition.
- Jeffery noted the "enabled by or interfaced with" does not account for closed-loop exchanges.
 - Hans said he would write down his questions/comments on that.
 - Jordan Everson said when standalone apps are embedded into a health IT module, he does not think the closed-loop exchange will apply. It is a nuanced topic.
 - Jim said even if the data flow is unidirectional to another app, the transparency requirement should still apply.
 - Hans agreed and said the difference between enabled by and interfaced with should be noted.
 - Jeffery noted there are numerous arrangements and data flows. When ONC put these descriptions together, they thought if the health IT module facilitates a DSI-output, ONC would consider that "being enabled or interfaced with" and the module would be subject to the transparency requirements.
- Steven Eichner asked if the DSI rules are subject to change as United States Core Data for Interoperability (USCDI) is updated.
 - Jeffery said yes, and the version of USCDI that this policy applies to is the current published version.
- Hans asked if a health IT module is compliant with USCDI version 4, are organizations obligated to upgrade to a newer version as it becomes available?
 - Jeffery said he would get back to Hans with an exact answer.



PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

No comments were received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Jim Jirjis: Jim jirjis joined

Steven Lane: Welcome task force members and interested members of the public. The public is welcome to use the chat feature to submit comments throughout the meeting and to take advantage of the verbal public comment period 10 minutes before the end of the meeting.

Steven Lane: Task force members, please use the hand raise feature.

Ian Sefferman: Can you share the URL to the Google Sheet?

Mike Berry (ONC): The Google sheet is a task force working document for task force members only. The progress of the task force will be displayed during public meetings. Thanks.

Ian Sefferman: Sounds good, thanks.

Hans Buitendijk: @Steven: Those would be good considerations to add as comments.

Hans Buitendijk: Including considerations whether FDA should or should not suggest to be certified as HIT (not specifically to EHR) to DSI module. That can raise confidence level as EHR interacting with DSI services, patient Apps interacting with those, etc.

Jim Jirjis: Eager to understand how external block box capabilities who can provide the details needed would be handled...large language models

Jim Jirjis: Cannot

Hans Buitendijk: So the module "calling" the module providing DSI capabilities that is certified must provide transparency, but the module being called that actually provides the DSI does not (unless it would be part of another certified HIT). Correct?

Steven Lane: Today's meeting recording will be posted to this link by the end of today:
<https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2>

Hans Buitendijk: Does that include DSI that the HIT supplier in other non-certified software they develop by virtue by having one being certified, or having to be certified?

Jim Jirjis: It seems like dsi created by third parties who do not comply or provide necessary information would lead to certified technology simply stating 'not available' frequently. The EMR for example would still be in compliance. Correct?

Medell K. Briggs-Malonson: +1 Jim

Jim Jirjis: So this is simply to ensure that certified technology provides the capability for transparency.

Jordan Everson: @Jim If I follow correctly, as proposed the EMR would still be in compliance so long as it indicates the information is not there. And users then could directly observe the absence of information as Jeff says.

Jim Jirjis: So fda would be the driver for third party compliance, this reuse



Jim Jirjis: so the fda would be the regulatory force requiring third parties to provide this info. This rule simply allows that information to be expressed in the workflow

Jim Jirjis: Would chatgpt3 be considered unsupervised machine learning technique?

Jim Jirjis: Even one way street may need transparency as to what the certified technology is sending you to...how compliant it is etc

Steven Lane: See also recently published ONC DSI and Predictive Models Fact Sheet:
www.healthit.gov/sites/default/files/page/2023-04/NPRM_DSI_fact%20sheet-508.pdf

Steven Lane: We need to move ahead with the presentation.

Steven Lane: This timing suggests that these requirements will initially reference USCDI V3 as this is also the data that V3 becomes the new standard.

Hans Buitendijk: We talked in a prior meeting about having an overview of all target dates across all elements. When would that be available to have full understanding of effort-timeline impacts?

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 – April 26, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

Adjournment

The meeting was adjourned at 11:59 AM.