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 31, 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 31 was to review and discuss the HTI-1 Proposed Rule Draft Recommendations.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Update and Revise Draft Recommendations
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
Hans Buitendijk, Oracle Health
Jim Jirjis, HCA Healthcare
Anna McCollister, Individual
Naresh Sundar Rajan, CyncHealth
Filipe (Fil) Southerland, Yardi Systems, Inc

Members Not in Attendance

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

ONC Staff
Mike Berry, Designated Federal Officer, ONC
Dustin Charles, ONC
Lana Moriarty, ONC
Maggie 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. The group 2 lead, Steven Eichner, reviewed the agenda and charge detailed in the May 31 meeting presentation materials.

Update and Revise Draft Recommendations
Steven Eichner led the review of Group 2's HTI-1 Proposed Rule Draft Recommendations document. A robust discussion followed.

Discussion:
- Anna McCollister noted she added eight additional comments to the recommendations document.
- Steven Eichner reviewed the first and second recommendations in Row 2 of the document.
  - Anna asked the Task Force to clarify the meaning of "robust" in the first recommendation.
    - Anna will draft adjustments to the recommendations offline.
- Steven Eichner reviewed the third recommendation in Row 2 of the recommendations document.
  - Fil Southerland said if a patient has a rare diagnosis, it should be considered when utilizing decision support interventions (DSI). There should be a framework for utilizing DSI in patients with rare diagnoses.
  - Anna recommended developers list out data elements that need to be present for the DSI to work as part of their approval process.
    - Steven Eichner disagreed and said that will not help differentiate situations where DSI should not be applied.
    - Anna noted there should be a feedback loop from clinicians to developers about real-world DSI use.
    - Hans Buitendijk said a DSI framework would be helpful. ONC needs to be careful about what data should or should not be included in DSI statements.
    - Jim Jirjis clarified the intent of this recommendation is to ensure technology has requirements to display DSI. The recommendation aims to help developers understand how to construct DSI with standards. Non-certified health IT third parties may be developing DSI that are integrated into certified health IT. The non-certified health IT third-party information needs to be presented in a way that can be integrated into an electronic health record (EHR).
      - Fil recommended ONC implement transparency requirements for patient characteristics and attributes utilized in DSI training. Training data should be available to EHRs in a standardized, computable format.
    - Steven Eichner said this recommendation will be revisited at the Task Force meeting on June 7.
- Steven Eichner reviewed the fourth recommendation in Row 2 of the recommendations document.

- o Hans asked if this could be in collaboration with the FDA's DSI work.
    - ▪ Steven Eichner said it is likely. This recommendation would not necessarily create a directory and would not require a new project for the developer. It would allow individuals to find the information they are looking for.
  - o The Task Force agreed on the recommendation.
- Steven Eichner reviewed the fifth recommendation in Row 2.
  - o The Task Force did not voice any concerns about the recommendation.
- Steven Eichner reviewed the sixth recommendation in Row 2.
  - o Hans recommended the documentation requirements change based on the United States Core Data for Interoperability (USCDI) scope. When a health IT module is updated through Standards Version Advancement Process (SVAP), the technology automatically supports the next USCDI version. Then the module also needs to be updated with the DSI documentation.
  - o The Task Force will revisit this recommendation at the meeting on June 7.
    - ▪ Hans will clarify his recommendation in the document before the meeting.
- Steven Eichner reviewed the seventh recommendation in Row 2.
  - o Anna said it would be helpful if ONC created a standard DSI label and then tested it. It will take a substantial amount of time but needs to be done and updated on a regular basis.
  - o Hans did not think the current Task Force recommendation has an actionable next step.
  - o Anna suggested the recommendation include ONC hosting a design contest.
    - ▪ The Task Force will revisit this recommendation next week.
- Steven Eichner reviewed the recommendations in Row 3 of the recommendations document.
  - o The Task Force approved the recommendations in Row 3.
- Steven Eichner reviewed the recommendations in Row 4.
  - o Hans said the "criterion" is the building block of certification. "Criterion" should be used throughout the recommendation.
  - o Steven Eichner said not all uses of "standard" can be replaced by "criterion."
    - ▪ Hans noted the standard is referenced in the criterion.
  - o Steven Eichner will rework the recommendation prior to the June 7 meeting.
- Group 2 will continue reviewing their recommendations at the next meeting on June 7.

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
Steven Lane: Welcome members of the public who are joining us this morning.

Steven Lane: Materials for today's meeting are located at https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-2-4

Steven Lane: The public is invited to participate in this public Webinar Chat and to take advantage of verbal public comment time at 11:50 ET.

Jim Jirjis: Jim Jirjis joined

Hans Buitendijk: A general statement that the DSI should provide documentation on data used, and situations where the DSI is not applicable as going into prescribing that relevant data upfront is highly complex.

Fil Southerland: Agree Hans - we need transparency on the training patient population for the DSI.

Hans Buitendijk: I put a potential clarification in Column K.

Jim Jirjis: I unfortunately have to log off at 11:30 eastern

Steven Lane: We will pause now for Public Comments.

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 31, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment
The meeting adjourned at 11:59 AM.