Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 3: Office of the National Coordinator (ONC) Health IT Certification Program Updates- Insights Conditions, Standards Updates, and RFIs

Meeting Notes | April 27, 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 session on April 27 was to review the HTI-1 Proposed Rule Task Force Charge and discuss the Insights Condition and Maintenance of Certification.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge and Topics Worksheet
10:45 AM	Insights Condition and Maintenance of Certification: Overview & Discussion
11:55 AM	Public Comment
12:00 PM	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, ONC, called the meeting to order at 10:30 AM.

Roll Call

Members in Attendance

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

Members Not in Attendance

Meg Marshall, Department of Veterans Affairs (VA)

ONC Staff

Mike Berry, Designated Federal Officer, ONC

Dustin Charles, ONC
Daniel Healy, ONC
Sara McGhee, ONC
Vaishali Patel, ONC
Maggie Zeng, ONC

Key Points of Discussion

HTI-Proposed Rule Task Force Charge and Topics Worksheet

HTI-1 Proposed Rule Task Force (Task Force) co-chairs, Steven Eichner and Steven Lane, welcomed attendees. Steven Lane reviewed the meeting agenda and Task Force charge detailed in the April 27 meeting presentation materials. Task Force members can join the other HTI-1 Task Force sessions in addition to the ones to which they have been assigned. All meetings will be open to the public. Hung Luu is the Group 3 lead and will help with facilitation during the Group 3 meetings. Steven Lane explained ONC created an HTI-1 draft recommendations working document. The document is internal to Task Force members, but the public can view it when it is displayed during the calls.

Insights Condition and Maintenance of Certification: Overview & Discussion

Vaishali Patel provided an overview of insights conditions measures, how the measures were developed, who reports on the measures, and how the information is submitted. Vaishali also recapped the reporting frequency, timeline, and key areas of review. She added ONC is hosting a webinar on May 11 that will further review the measures. Task Force members are welcome to register for the webinar using the link here. The group also reviewed the individual access to electronic health information (EHI) measure in greater detail.

Discussion:

- Steven Lane asked where the numbers, such as 50 hospitals or 500 clinician users, in the measure came from.
    - ○ Vaishali Patel said the numbers came from the Center for Medicare and Medicaid Services (CMS) 2019 Promoting Interoperability Measures publication. The thresholds were built off the concept that 99% of hospitals and 99% of clinicians would be represented.
        - ▪ She additionally clarified the hospital threshold was not 50 hospital users but 50 hospitals.
- Hung Luu asked about the data aggregation in the reporting measures. If there are three versions of a health IT module, but only one meets the criteria, do all versions get certified? Are they able to market the versions the same way?
    - ○ Vaishali said ONC would only certify the versions that do meet the criteria.
- Hans Buitendijk said the cadence in the reporting frequency looks good, but there will be some challenges that come up.
    - ○ He noted it is helpful that ONC's timeline displays year 1 and year 2; however, in the Proposed Rule, it indicates exact years, such as 2023 and 2024.
    - ○ Hans also mentioned there will be challenges where this is a requirement for electronic health records (EHRs) to report on. This data will need to come from the EHRs clients. The Task Force should be considerate of the contracts EHRs and their clients have in place.
    - ○ Vaishali thanked Hans for flagging those points. She requested Hans indicate his concerns, and any potential solutions or suggestions, in the recommendations document.

- Fil Southerland asked if these guidelines would advance over time. Is it subject to additional rulemaking?
  - Vaishali said this proposed set of measures represents interoperability. Congress also asked for measures in other areas, such as usability, user-centered design, and security. She noted it would likely depend on the experience with this round of comments.
- Fil asked about the "clinician" definition in the Proposed Rule. Does it include nursing staff as well?
  - Vaishali said she doesn't think "clinician" has been defined in the rule. However, the use of "clinician" in this context is not meant to only include physicians.
  - Steven Lane noted in his experience, clinician is broader and includes pharmacists, nursing staff, and more.
- Steven Lane said there is value in ramping up the reporting frequency and timeline. He noted there are other efforts out there focused on reporting metrics around EHRs.
  - Vaishali said the goal of the insights condition is not focused on comparing EHR developers; it is focused on reporting transparency. ONC does not want to duplicate efforts that already exist.
    - ONC's current measurement tactic is largely survey-based.
- Vaishali noted it has been difficult to get patients to self-report their access to EHI. Apps are marketed in various ways, and it is challenging for patients to differentiate where the EHI is coming from (portals, apps, etc.).
- Steven Lane noted there is a year 1 and year 2 progression. He anticipates there will be learnings and challenges that come up, and the methodology may need to change. Will that require additional rules to define what this looks like in years 3 and 4?
  - Vaishali deferred to ONC's regulatory affairs division.
- Hans asked if there are aspirations to align this with Contextual Query Language (CQL) or Fast Healthcare Interoperability Resources (FHIR).
  - Vaishali said she appreciates Hans raising that notion and will follow up with him afterward.
- Vaishali said when the individual access to EHI measure was initially proposed, ONC considered breaking this down based on patient demographics. However, the 2021 Health Information Technology Advisory Committee (HITAC) advised it would be too difficult, so ONC decided not to move forward.

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
Mike Berry (ONC): Thank you for joining the HTI-1 Proposed Rule Task Force, Group 3 meeting! Slides/agenda is available at: https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-3

Mike Berry (ONC): Please remember to tag "Everyone" when using Zoom chat so that we can see your message. Thanks!

Mark Savage: Will stratification variables differ or expand for different measures, not just, say, structural or operational variables? The choice of stratification variables matters. For example, could really help improve *health equity" to stratify measures of individual or patient access by demographic elements such as race, ethnicity, sexual orientation, gender identity, disability, etc. This gives significant additional insight for health equity or health disparities.

Vaishali Patel: https://www.healthit.gov/news/events/hti-1-proposed-rule-information-sessions

Mark Savage: Task Force could consider anew question of stratification variables, given that much has happened over the two years that have passed.

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 27, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting was adjourned at 12:00 PM.