

# Health Information Technology Advisory Committee

## HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

### Full Task Force Meeting

## Meeting Notes | June 7, 2023, 10:30 AM – 12 PM ET

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### Executive Summary

The focus of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Full Task Force session on June 7 was to review, discuss, and revise the HTI-1 Proposed Rule Task Force 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  
Steven Lane, Health Gorilla, Co-Chair  
Hans Buitendijk, Oracle Health  
Hannah Galvin, Cambridge Health Alliance  
Hung Luu, Children's Health  
Anna McCollister, Individual  
Clem McDonald, National Library of Medicine  
Eliel Oliveira, Dell Medical School, University of Texas at Austin  
Kikelomo Oshunkentan, Pegasystems  
Naresh Sundar Rajan, CyncHealth  
Filipe (Fil) Southerland, Yardi Systems, Inc

#### Members Not in Attendance

Medell Briggs-Malonson, UCLA Health  
Adi Gundlapalli, CDC



Jim Jirjis, HCA Healthcare  
Deven McGraw, Invitae Corporation  
Aaron Miri, Baptist Health  
Sheryl Turney, Elevance Health

## ONC Staff

Mike Berry, Designated Federal Officer, ONC  
Sara McGhee, ONC  
Michael Wittie, ONC  
Maggie Zeng, ONC

## Key Points of Discussion

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### HTI-1 Proposed Rule Task Force Charge

HTI-1 Proposed Rule Task Force (Task Force) Co-Chairs, Steven Eichner and Steven Lane, welcomed attendees. Steven Eichner reviewed the meeting agenda and charge detailed in the [June 7 meeting presentation materials](#).

### Update and Revise Draft Recommendations

Steven Eichner led the review of the HTI-1 Proposed Rule Task Force Draft Recommendations document. A robust discussion followed.

#### Discussion:

- Steven Eichner reviewed Recommendations 1 and 2 in Row 4 of the document.
  - The Task Force approved Recommendation 1 in Row 4.
  - Hans Buitendijk suggested a slight grammatical adjustment to Recommendation 2.
    - The Task Force approved the recommendation.
- Steven Eichner reviewed Recommendation 3 in Row 4.
  - Hans suggested noting that ONC should look not only at the total impact of the certification program but also at the other health information technology (HIT) work in the industry that will need upgrades and training.
  - The Task Force approved the recommendation.
- Steven Eichner reviewed Recommendation 4 in Row 4.
  - The Task Force approved the recommendation.
- Steven Eichner reviewed Recommendation 5 in Row 4.
  - Fil Southerland said CMS incentive programs are based on certified electronic health record (EHR) technology. Since the Centers for Medicare and Medicaid (CMS) definition of certification differs from ONC's, modular certified HIT systems are excluded from the certification program, and it has significant impacts on the specialty EHR sector.
  - The Task Force agreed on the recommendation.
- Steven Eichner reviewed Recommendation 1 in Row 7 of the document.
  - Hans voiced concerns about the timelines.
    - Steven Lane agreed and suggested Hans' concerns be moved to Tab 1. Tab 2 will be more specific feedback for future restrictions.
  - Hannah Galvin said mapping would be needed for this recommendation. It takes time to develop, and she does not think this recommendation should be included.



- Steven Lane moved the recommendation to Tab 1.
- Steven Eichner reviewed Recommendation 2 in Row 7.
  - Hannah said the industry is not ready for this certification. The industry should come together to work on it, but she thinks a 5-year maturity model is needed.
  - Hans said the level of clarity needed for patients to effectively manage their preferences is not currently available. He suggested pushing Recommendation 10 in Row 7 down and focusing on Recommendations 1-3.
  - Eliel Oliveira said the Task Force should consider how consent setup works first. To solve basic consent, the data collected needs to be queried electronically.
- Hannah noted Recommendations 2 and 3 in Row 7 are current recommendations to work with stakeholders. It is not asking for certification but is just starting the process.
  - Steven Eichner said there needs to be alignment between Recommendations 2, 3, and 10.
  - Hans said if what is being proposed now is premature, the Task Force should not recommend moving forward until the standards are in certification.
  - Hannah agreed with Hans and said the dependencies should be included in the recommendation.
  - The Task Force agreed to add that “ONC should pursue a standards-based approach” to Recommendation 2 of Row 7.
- Steven Eichner reviewed Recommendation 4 in Row 7.
  - Anna McCollister said this recommendation is important because it indicates patients can restrict their own data. Patients should understand how their data is being used. If there is a lack of trust from the public, it will be a huge issue.
  - Steven Eichner disagreed with Steven Lane’s comment that this recommendation does not relate to ONC’s ask. He said it is important for this recommendation to be included because it relates to how patients want their data shared.
    - Anna agreed. Patients may not want every clinician to see their full medical data. If patients understand when certain data is used, it will increase trust.
  - Hannah said there is ongoing work with granular segmentation. It is a balancing act between privacy, patient safety, and consent.
  - The Task Force approved Recommendation 4.
- Steven Eichner reviewed Recommendation 5 in Row 7.
  - Hans said Recommendations 5 and 6 could be added as sub-topics under Recommendation 10.
  - Clem McDonald noted lots of clinical data is free text. There is no simple way to isolate that information.
  - The Task Force agreed to suggest “use of a piloting approach and strategic discussion” to the recommendation. The group approved Recommendations 5 and 6.
- Steven Eichner reviewed Recommendation 7 in Row 7.
  - The Task Force approved.
- Steven Eichner reviewed Recommendation 8 in Row 7.
  - The Task Force approved.
- Steven Eichner reviewed Recommendation 9 in Row 7.
  - Hans suggested moving Recommendation 9 to a sub-topic under Recommendation 10.
    - The Task Force agreed.
- Steven Eichner reviewed Recommendation 11 in Row 7.
  - Hans suggested Recommendation 11 be removed. It has been addressed under Recommendation 10 and its sub-topics. The second sentence of Recommendation 11 can be added to Recommendation 12. He will amend the recommendations offline.
  - The Task Force approved.
- Steven Eichner reviewed Recommendation 12 in Row 7.
  - Hans said he will minorly amend the recommendation grammar offline.



- The Task Force approved the recommendation.
- Steven Eichner revisited Row 2 in the document.
  - The Task Force approved Recommendation 1 in Row 2.
  - The Task Force approved Recommendation 2.
  - Fil suggested “physicians” be broadened to “clinicians” in Recommendation 3.
    - The Task Force approved Recommendation 3.
  - The Task Force approved Recommendation 4.
  - The Task Force approved Recommendation 5.
  - The Task Force approved Recommendation 6.
  - The Task Force approved Recommendation 7.
    - Fil noted the phrase “limit” may be too strong here.
    - The Task Force decided to keep the recommendation as is.
  - The Task Force approved Recommendation 8.
- A copy of the draft Recommendations Document will be shared after the Task Force meeting on June 8.

## **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**

Betty Lengyel-Gomez: Second recommendation indicator is misspelled as indivator

Hans Buitendijk: Suggest adding to first sentence of the recommendation "....., including all other HIT updates that need to be managed as well."

Betty Lengyel-Gomez: Recommendation 5 should it state CMS program requirements such as MIPS instead of requires?

Hannah K. Galvin: I agree, Hans. We need to align around a few use cases for standards development and then consensus-based implementation guidance.

Hannah K. Galvin: It sounds like we endorse the standards-based approach (10), but highlight the dependency and need for a maturity model

Hans Buitendijk: On 10 a suggestion to adjust the first sentence to "Recommend that ONC utilize a standards-based approach based on the following standards:"

Hannah K. Galvin: (Hans captured my question)

Steven Lane: @Hans: Change made

Eliel Oliveira: All good Steven. Thanks

Clem McDonald: think Anna's position is right on. But we do have to move on.

Noam Arzt: And note that since the public cannot see this work in process we will not have an opportunity to comment if time runs out, right?

Hannah K. Galvin: I support an iterative approach, involving a broad stakeholder group. Granular segmentation and consent leverage different standards, both of which are necessary to achieve the goal



here. While the LEAP group piloted the FHIR consent standard, it needs to be paired with data segmentation standards and profiles as well as a semantic conceptual model, and consensus-driven implementation guidance.

Hans Buitendijk: @Eliel: Agreed we need not limit to the LEAP project, but certainly should learn from it on how to enable a "central" patient consent rule/policy set that that the patient can maintain and "follow" their data holders so everybody can manage the data according to the same, up-to-date policies/rules.

Eliel Oliveira: Exactly @Hans. We do not have a defined architecture tested yet and although the LEAP project provided great insights, it is unclear if it will work in real practice and scale.

Hans Buitendijk: I suggest 11 has been covered by 10 and all its components.

Hans Buitendijk: Suggestion on new #12: "12 - Recommend that ONC clarify technology support for the exchange of flow down requirements including requirements within TEFCA. This should particularly address elements of the FHIR Trust Contract profile with Labeling Capability Statements for real-time verification that applies when sender/receiver are bound under agreements such as eHealth Exchange DURSA or the QHIN Technical Framework and consistently applied to any exchanges under TEFCA."

Julie Maas: Re: previous topic, I would note that in addition to trust framework membership as validated by a UDAP certificate, the HL7 UDAP Security working group has discussed UDAP certifications as a mechanism to carry information about relevant DURSAs or other contracts as part of the authorization workflow. Contracts could be used as part of the payload for this.

Eliel Oliveira: Great meeting all!

Eliel Oliveira: 🙌

## 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 – June 7, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

## Adjournment

The meeting adjourned at 11:59 AM.