

Health Information Technology Advisory Committee (HITAC)

VIRTUAL

Meeting Notes | May 17, 2023, 10 AM – 11:30 AM ET

EXECUTIVE SUMMARY

The HITAC Co-Chairs, **Medell Briggs-Malonson** and **Aaron Miri** welcomed members, reviewed the meeting agenda, and presented the minutes from the April 12, 2023, HITAC meeting, which were approved by voice vote. **Micky Tripathi**, National Coordinator for Health IT, Office of the National Coordinator (ONC), welcomed attendees to the meeting and provided a status update on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule since its release in April 2023. **Steven Eichner** and **Steven Lane**, HTI-1 Proposed Rule Task Force Co-Chairs, reviewed the Task Force's membership, charge, progress, and timeline. **Lisa P. Goldstein**, Health Information Privacy, Data, and Cybersecurity Policy Specialist, HHS Office for Civil Rights, presented on the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to Support Reproductive Health Care Privacy. There was a robust discussion in the public meeting chat via Zoom throughout the meeting.

AGENDA


10:00 AM	Call to Order/Roll Call
10:05 AM	Welcome Remarks
10:15 AM	Opening Remarks, Review of the Agenda and April 12, 2023, Meeting Notes – HITAC Vote
10:20 AM	Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule Task Force Update
10:50 AM	Office for Civil Rights Proposed Rule – HIPAA Privacy Rule to Support Reproductive Health Care Privacy
11:20 AM	Public Comment
11:30 AM	Final Remarks and Adjourn

CALL TO ORDER/ROLL CALL

Mike Berry, Designated Federal Officer, ONC, called the May 17, 2023, meeting to order at 10:02 AM and welcomed ONC's executive leadership team to the call.

ROLL CALL

Medell Briggs-Malonson, UCLA Health, Co-Chair
Aaron Miri, Baptist Health, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Sarah DeSilvey, Larner College of Medicine, University of Vermont



Steven (Ike) Eichner, Texas Department of State Health Services
Cynthia A. Fisher, PatientRightsAdvocate.org
Lisa Frey, St. Elizabeth Healthcare
Hannah Galvin, Cambridge Health Alliance
Valerie Grey, State University of New York
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Steven Hester, Norton Healthcare
Jim Jirjis, HCA Healthcare
Steven Lane, Health Gorilla
Hung S. Luu, Children's Health
Arien Malec, Change Healthcare
Anna McCollister, Individual
Deven McGraw, Invitae Corporation
Aaron Neinstein, UCSF Health
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Kikelomo Adedayo Oshunkentan, Pegasystems
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.

HITAC MEMBERS NOT IN ATTENDANCE

Bryant Thomas Karras, Washington State Department of Health
Kensaku (Ken) Kawamoto, University of Utah Health
Clem McDonald, National Library of Medicine
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

FEDERAL REPRESENTATIVES

Thomas Cantilina, Military Health System, Department of Defense (DoD) (*Absent*)
Adi V. Gundlapalli, Centers for Disease Control and Prevention (CDC)
Ram Iyer, Food and Drug Administration (FDA) (*Absent*)
Meg Marshall, Department of Veterans Affairs (*Absent*)
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Seth Pazinski, Director, Strategic Planning and Coordination Division
Mike Berry, Designated Federal Officer

WELCOME REMARKS



Micky Tripathi welcomed attendees on the call. He explained that since the release of the ONC HTI-1 Proposed Rule, ONC has been conducting educational outreach on individual aspects of the Proposed Rule. The next Proposed Rule Webinar will be on May 18 at 1 PM ET and is focused on information blocking. The public comment period is open until June 20, 2023.

Micky noted that the 2023 Leading Edge Acceleration Projects (LEAP) in Health IT program issued a new Special Emphasis Notice for the 2023 LEAP in Health IT projects. The two main areas are exploring advanced fast health care interoperability resources (FHIR) capabilities and identifying data quality improvements for United States Core Data for Interoperability (USCDI) elements. Micky also reminded attendees that the June 2023 HITAC meeting will be in-person in Washington, DC. There will be a virtual option for those unable to join in person.

Shila Blend, North Dakota Health Information Network, disclosed she has been appointed to work with the Center for Medicare and Medicaid Services (CMS) and Yale University in their Center for Outcomes Research and Evaluation on interoperability items as part of a volunteer workgroup.

Opening Remarks, Review of Agenda and April 12, 2023, Meeting Notes – HITAC Vote

Medell Briggs-Malonson and **Aaron Miri**, HITAC Co-Chairs, welcomed attendees. **Aaron** thanked the HTI-1 Proposed Rule Task Force teams for their hard work and reviewed the agenda. **Medell** called for a motion to approve the April 12, 2023, HITAC meeting notes.

Aaron motioned to approve the notes. This motion was seconded by **Jim Jirjis**. **The HITAC approved the April 12, 2023, meeting notes by voice vote. No members abstained and no members opposed.**

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule Task Force Update

Steven Lane, Task Force Co-Chair and Group 1 Lead, thanked the ONC team for their tremendous support with the HTI-1 Task Force meetings. Steven reviewed the HTI-1 Proposed Rule Group 1 topics, which center around Information Blocking. He also reviewed the Task Force membership, charge, and past and upcoming meeting topics.

Steven Eichner, Task Force Co-Chair and Group 2 Lead, recapped HTI-1 Proposed Rule Group 2 topics, which focus on: ONC Health IT Certification Updates and New and Revised Certification Criteria, past and upcoming meeting topics and highlighted the invited external subject matter experts (SMEs) that will be joining future meetings.

Hung Luu, Group 3 Lead, walked through the HTI-1 Proposed Rule Task Force Group 3 topics, which include: ONC Health IT Certification Program Updates, such as Insights Conditions, Standards Updates, and Request for Information (RFIs), past and upcoming meeting topics and noted the invited external SMEs joining future meetings. The HTI-1 Proposed Rule Task Force recommendations will be formally presented to the HITAC at the June 15, 2023, meeting.



Discussion:

- **Anna McCollister** voiced her concerns on the Proposed Rule as a patient advocate by noting that sixty days is not long enough to digest the lengthy Proposed Rule and provide comments. She said changes in the Proposed Rule will impact many patients who do not know about it.
- **Steven Lane** noted a patient advocate, Grace Cordovano, spoke to the Task Force on May 3, 2023. He stated it was helpful to hear her perspective on how the Proposed Rule will impact patients and the considerations ONC should take with decision support intervention (DSI) transparency. In Task Force meetings, there have also been discussions about specialty electronic health records (EHRs) being required to fully comply with USCDI standards to certify, despite several data elements not applying to them.
- **Fil Southerland** noted the Task Force is generally supportive of the move from USCDI version 1 to version 3. However, it is a big lift for specialty EHRs to comply fully with USCDI. Anecdotally, he stated he works in elder post-acute care, and his organization's EHR must accommodate pediatric endpoints.
- **Steven Eichner** agreed and noted it is important to ensure HITAC's eyes are kept on public health agencies so disaster response and public health crises are addressed quickly and effectively.

Office for Civil Rights Proposed Rule – HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Lisa P. Goldstein, Health Information Privacy, Data, and Cybersecurity Policy Specialist, HHS Office for Civil Rights, highlighted the current [HIPAA Privacy Rules and the Proposed Rule Highlights](#), including proposed attestation, disclosures to law enforcement, and notice of privacy practices. The HHS Office for Civil Rights released its Proposed Rule in April 2023 and welcomes comments on the Proposed Rule by June 16, 2023.

Discussion:

- **Medell Briggs-Malonson** said this Proposed Rule has significant implications, especially in states where reproductive rights are restricted. She thanked Lisa for her overview and encouraged the HITAC members to provide comments.
- **Alexis Snyder** voiced concerns about patients and families disregarding the privacy information when it is handed to them. She suggested that privacy information should be provided to patients in plain language, at appointment check in, and patients should be made aware that this is important information for them to access and review before signing off on.
 - **Lisa Goldstein** said the Privacy Rule has requirements pertaining to that. If a provider is not providing that information to patients, patients can file a complaint, and the HHS Office for Civil Rights can investigate.
 - **Steven Eichner** asked Lisa to discuss how pregnancy status, for example, is impacted from a public health perspective with this Proposed Rule.
 - **Lisa** said under HIPAA, the Privacy Rule cannot preempt state law with reporting public health measures. In the Proposed Rule, the HHS Office for Civil Rights proposed clarifying what needs to be reported at the state level. The reporting requirements depend on the purpose of the reporting, such as civil, criminal, or administrative reporting.
 - **Eliei Oliveira** said the Privacy Rule is focused on reproductive health and asked if this protection could be broadened under the Fifth Amendment.
 - **Lisa** noted the Privacy Rule permits individuals to request restrictions that a covered entity not disclose their information to others. She encouraged Eliei to provide



comments on the Privacy Rule so the HHS Office for Civil Rights can consider further.

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

Jim Jirjis: Have I joined late?

Mike Berry (ONC): Welcome to the May 2023 HITAC meeting. Your comments are welcome in Zoom chat throughout the meeting. Please tag "Everyone". Meeting materials can be found at: <https://www.healthit.gov/hitac/events/health-it-advisory-committee-56>

Ram Sriram: What is the link for the Blog on AI in Healthcare?

Wendy Noboa: Blog Post - Increasing the Transparency and Trustworthiness of AI in Health Care: <https://www.healthit.gov/buzz-blog/health-innovation/transparent-and-trustworthy-ai-in-health-care>

Aaron Miri: Cannot wait to see everyone again for the in-person HITAC in June.

Accel Solutions: You can register for the June HITAC meeting here: <https://www.healthit.gov/hitac/events/health-it-advisory-committee-57>

Steven Lane: The ONC blog series on AI & ML was particularly helpful in laying a foundation of understanding for the taskforce's DSI discussion: <https://www.healthit.gov/buzz-blog/category/blog-series-artificial-intelligence-machine-learning>

Donna Doneski: 100% agree, Fil. We at ADVION are preparing comments/ recommendations. Thanks.\

Steven Lane: E.g., pediatric head circumference, as Fil noted, may not apply to ALL EHI that would benefit from certification.

Hans Buitendijk: Agreed with Ike and Fil. Within both USCDI and draft USCDI+ data sets the ability to more dynamically enable a variety of HIT to participate and yield predictable, consistent interoperability capabilities.

Medell K. Briggs-Malonson: Thank you HTI-1 Task Force and ONC. We look forward to reviewing the task force recommendations in the near future.

Steven Lane: HTI-2: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA06>

Seth Pazinski: Here are the links to the other ONC rules included in the Unified Agenda...

Seth Pazinski: "Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking" <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA05>

Seth Pazinski: "Patient Engagement, Information Sharing, and Public Health Interoperability" <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA06>

Susan Clark: Thank you @Seth & Steven for sharing the OMB links for upcoming rulemaking!



Steven Lane: Thank you, Lisa for this excellent and thorough presentation, which is available at https://www.healthit.gov/sites/default/files/facas/2023-05-17_OCR_%20Proposed_Rule_HIPAA_Privacy_Rule_to_Support_Reproductive_Health_Care_Privacy_Presentation.pdf

Steven Lane: Nearly all requests for comprehensive clinical data for adolescents and adults born female and many for those born male will/should include “PHI potentially related to reproductive health care”.

Mark Savage: PSA campaign would help!

Deven McGraw: @Alexis, good question - I think there are limits to OCR’s reach in educating the public about this - I think there is a role for educating patient advocacy groups, who are then in a terrific position to translate this to their populations. Similarly for making sure trusted medical providers are aware and can address any questions.

Deven McGraw: OCR’s not trying to regulate lawmakers but instead to keep those lawmakers from getting at the information that was generated through a lawful medical procedure and misusing it.

Eliel Oliveira: Thank you Lisa

Aaron Miri: I am curious on the intersection point here between OCR and FTC on this rule for Health IT vendor companies that refuse to comply with HIPAA (e.g.: signing a BAA) and what recourse a provider may have to enforce that necessity around ePHI (reproductive data or not) besides simply not using that vendor or product. Is there an avenue for reaching out to the OCR or other’s to broker a conversation on the importance of privacy?

Deven McGraw: @Aaron, if a health IT vendor company is a BA the failure to sign a BAA is a HIPAA violation. Signing or not signing a BAA is not what triggers BA coverage - as an entity you either meet the definition of BA or you don’t. The proposed rule would apply to BAs. But OCR can’t reach entities not covered by HIPAA. Congress has to act to do that.

Wendy Noboa: HTI-1 Proposed Rule Information Sessions: <https://www.healthit.gov/news/events/hti-1-proposed-rule-information-sessions>

Steven Lane: Thank you to ONC and the HITAC co-chairs for an excellent and engaging meeting.

Wendy Noboa: Learn more and register on the ONC Events page: <https://www.healthit.gov/newsroom/events>

Aaron Miri: @deven - thank you. That’s my point. I feel there’s a gap here between oversight to ensure privacy is first and foremost. The rule goes far but does it go far enough is my question

Steven Lane: At the 6/5 meeting on access to test results, please include the need to promote access to results directly from performing laboratories.

Steven Lane: Patients and their providers should not be blocked from access to ALL of a patient’s past lab results to inform care.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.



FINAL REMARKS

Mike Berry reminded members that the next meeting of the HITAC will be held virtually and in person on June 15, 2023, in Washington, DC. All materials and testimony from today's meeting will be made available at <https://www.healthit.gov/hitac/events/health-it-advisory-committee-56>.

Seth Pazinski invited the HITAC and the public to attend the May 25 "ONC Tech Forum: Sink Your Teeth into Sync for Genes" and the first meeting of the "ONC Tech Forum: Clinical Decision Support Series" on June 7. An HTI-1 Proposed Rule Information Session on "Impacts to Patients and Caregivers" will also be held on June 1. A "Policy in Practice: Supporting Ready Patient Access to Test Results" will also be held on June 5. All meeting details and information can be found here: <https://www.healthit.gov/newsroom/events>.

Aaron Miri and **Medell Briggs-Malonson** thanked attendees for their participation.

ADJOURN

The meeting adjourned at 11:30 AM.