

Meeting Notes Health Information Technology Advisory Committee Information Blocking Task Force March 15, 2019, 11:30 a.m. – 12:30 p.m. ET Virtual

The March 15, 2019 meeting of the Information Blocking, Assurances, & Communications Conditions of Certification Task Force (IACCTF) of the Health IT Advisory Committee (HITAC) was called to order at 11:30 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

MEMBERS IN ATTENDANCE

Michael Adcock, Co-Chair, Individual Andrew Truscott, Co-Chair, Accenture Cynthia Fisher, Member, WaterRev, LL Valerie Grey, Member, New York eHealth Collaborative Anil Jain, Member, IBM Watson Health John Kansky, Member, Indiana Health Information Exchange Steven Lane, Member, Indiana Health Information Exchange Steven Lane, Member, Sutter Health Arien Malec, Member, Change Healthcare Denni McColm, Member, Citizens Memorial Healthcare Aaron Miri, Member, The University of Texas at Austin, Dell Medical School, and UT Health Austin Sasha TerMaat, Member, Epic Denise Webb, Member, Individual

MEMBERS NOT IN ATTENDANCE

Sheryl Turney, Member, Anthem Lauren Thompson, Member, DoD/VA Interagency Program Office

ONC STAFF

Cassandra Hadley, HITAC Backup/Support Penelope Hughes, Staff Lead Mark Knee, Staff Lead Lauren Richie, Branch Chief, Coordination, Designated Federal Officer Lauren Wu, ONC SME

Call to Order

Michael Adcock thanked all of the members and the ONC staff for their help coming up with the current version of the recommendations.

Workgroup 1: Relevant Statutory Terms and Provisions Progress **TOPICS DISCUSSED**

- Health information networks/exchanges
 - Proposal: Distinction between HIE and HIN should be clearer.
 - Discussed whether the definitions would cover the broad scope of entities that such terms should cover based on the intent of Cures.
 - Proposal: Revise definition of HIE to mean "an individual or entity that enables, facilitates, or performs the access, exchange, processing, handling or other use of electronic health information."
 - Still working through HIN definition.
- EHI definition
 - Proposal: Add text in preamble that clarifies that "information" is inclusive of human or machine-readable form.
- Price information
 - Consensus that proposed definition of EHI should be read to include price information.
 - Workgroup will review ONC's RFI regarding price information and provide more detail about the scope and parameters of price information that would be included and the implications of including such information in the definition.

Workgroup 2: Exceptions Progress TOPICS DISCUSSED

- Promoting the Security of EHI
 - Proposal: Clarify the documentation requirement for when the practice does not implement an organizational policy.
 - Consensus that when the requestor is the data subject (patient), then security is no reason to prevent sharing unless there is legitimate doubt of the identity of the patient; determining whether the current drafting requires a proposed recommendation.
- Responding to Requests that are Infeasible
 - Discussion of meaning and application of providing a "reasonable alternative."
 - Group thinks the requirement that the actor "timely respond" is unclear; determining whether to propose a revision/clarification.
- Licensing of Interoperability Elements on RAND Terms
 - Proposal: Add requirement that licensors must publicly post contact info for requestors to contact them and requirement that requestors must use that publicly posted list to contact licensors.
 - Proposal: 10-day response period in (a) is unreasonable for offering license.
 - Considering proposing alternate time frame.
 - Proposal: Build in timeframe for licensor to acknowledge receipt of request into the overall response timeline.
 - Suggestion of 72 hours to acknowledge receipt.
 - Considering proposal to clarify the scope of rights.
 - Did not get through the entire exception.

Workgroup 3: Conditions and Maintenance of Certification Progress

TOPICS DISCUSSED

Michael Adcock noted that the proposals detailed do not reflect the most recent language refinements that were discussed at the last meeting of this workgroup.

- Assurances
 - Proposal: 3-year retention period for products that are withdrawn.
 - Proposal: ONC should retain records on the CHPL indefinitely for ongoing reference of which products were certified over which time period.
 - Proposal: Revisit TEFCA RFI to make recommendations when revised draft of TEFCA is published (or have the other TEFCA task force address it).
- Communications
 - Proposal: Clarify that administrative functions could be "non-user facing aspects."
 - Determining how to address the issue; possibly through functional definition or examples in preamble.
 - Proposal: Unintended consequences of "fair use" and other usages should be further explored by ONC. There are concerns about risks to vendor intellectual property that the task force wishes to be sensitive to; we do not wish to impinge upon innovation.
 - Proposal: Draw a distinction around purpose of use regarding screenshots.
 - Still determining details of proposal.
 - Proposal: Clarify via a list which third-party content might appear in a screenshot. Enumerating elements per screen is not feasible.
 - Proposal: Eliminate 2-year timeframe for contract amendment and propose update at next renewal.
 - Proposal: Unintended consequences of "fair use" and other usages should be further explored by ONC. There are concerns about risks to vendor intellectual property that the work group wishes to be sensitive to; do not want to impinge upon innovation.

 — Proposal: Create 3rd communication bucket for "unprotected" communications (i.e., false communications, attorney-client privilege, etc.).
- Enforcement
 - Proposal: Use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination.
- Ban
 - Discussion of whether appropriate to list ban that is lifted, and if so, what the appropriate time period would be.
- Self-developers
 - Proposal: Call out an exception to proposed § 170.403(a)(2)(ii)(A) (Communications) for selfdeveloped systems, so that communications by health IT users aren't restricted by virtue of being employees of the same company doing the development.

Group Discussion of Big Picture/Overarching Issues

Michael Adcock thanked the members for all their hard work and the future work to come. He also noted his appreciation for the respect that members have shown each other, even when their perspectives have differed.

Andy Truscott encouraged members to provide any necessary updates to their shared Google document for each of the workgroups. This will help the co-chairs prepare for the discussion with the HITAC and ensure that all opinions are included in the recommendations.

He also encouraged simplification whenever possible. Removing verbose draftsmanship will help with interpretation going forward.

John Kansky commented that he shares the need for there to be more fluid information across health care systems for patients, but any vagueness or lack of clarity just makes it harder for compliance. Any confusion has the potential to lead to claims of information blocking that will need to be adjudicated. The degree to which simplification can be achieved in the definitions and the requirements of the regulation will have a significant impact.

Arien Malec commented that he expected to see a safe harbor practice that would be considered reasonable under information blocking. He was expecting to see a correlation between the Trusted Exchange Framework and Common Agreement (TEFCA) and information blocking. He shares the premise that the current exception-based approach creates complexity. He endorses approaches to simply. One way to do this is to enumerate the actions that when compiled with would be presumed to not be information blocking.

Cynthia Fisher agreed with John Kansky's remarks. She believed the intention of information blocking is to keep it broad. She emphasized the importance of clarifying terms and definitions.

John Kansky said it would simplify compliance with the regulation if examples were provided. Examples whenever possible would be helpful for clarification and interpretation for the public.

Andy Truscott asked the group to comment on whether there is a consensus that the intention of information blocking is to touch upon any entity that is processing electronic health information.

- Arien Malec suggested depicting fringe examples and determining whether information blocking would apply (e.g., banking).
- John Kansky said it is very easy to say that everyone should be included, but the way the definitions of the actors are written, a lot of organizations will be brought in that goes beyond the intent. It could be a regulatory burden if all organizations were included (e.g., banking, Uber).
- Andy Truscott expressed concern that non-compliance could happen in this scenario.
- Sasha TerMaat mentioned that some of the provisions could have unintended consequences on clinical research.
- **Denni McColm** mentioned companies that are reporting to state cancer registries who wouldn't have the authority to be sharing the information.
- Andy Truscott emphasized the importance of the definitions being well constructed.
- **Aaron Miri** mentioned substance abuse and sharing of that data, to the degree the rule can help remediate and standardize these processes it would be helpful.
 - Andy Truscott asked Mark Knee to help gather information on this.
- **Cynthia Fisher** emphasized that the intention is to provide relevant information to patients to improve their health. Patients need access to manage their care.

• Arien Malec noted the goal is to provide greater access to patients, improve care, and improve operations associated with healthcare transformation. Does the proposed regulatory framework serve this need and/or does it cause a burden on the healthcare system?

Steven Lane asked what would be included in the recommendations during next week's HITAC.

- **Andy Truscott** commented that the co-chairs are working on refining recommendations and the majority of what was discussed today will be shared.
- **Michael Adcock** also noted that there will be additional opportunities to provide input on the recommendations as the workgroups are still refining and continuing their work.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

Lauren Richie adjourned the meeting at 12:25 p.m. ET.