Meeting Notes

Health Information Technology Advisory Committee
Information Blocking Task Force
May 03, 2019, 11:00 a.m. – 12:30 p.m. ET
Virtual

The May 03, 2019 meeting of the Information Blocking Task Force (IB) of the Health IT Advisory Committee (HITAC) was called to order at 11:00 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

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

MEMBERS NOT IN ATTENDANCE

Denni McColm, Member, Citizens Memorial Healthcare

ONC STAFF

Cassandra Hadley, ONC
Mark Knee, ONC Staff Lead
Morris Landau, ONC Staff Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Lauren Wu, ONC SME

Call to Order
Lauren Richie called the meeting to order and turned the meeting over to Andrew Truscott, co-chair.

Request for Information Regarding Trusted Exchange Framework and Common Agreement (TEFCA)

Mark Knee shared that there will be a separate Trusted Exchange Framework and Common Agreement (TEFCA) task force. In regards to the charge for the Information Blocking Task Force, there are two requests for information related to TEFCA in the notice of proposed rulemaking (NPRM) that this task force has been asked to respond to and discuss during today's meeting.

Arien Malec commented that having an affirmative set of obligations for actors to conform to that provide the effect of a safe harbor would be useful because it would drive actors to set-up appropriate standards to comply with the TEFCA capabilities.

- **Andy Truscott** asked if trusted exchange framework (TEF) should be the safe harbor or it should not be?
- **Arien Malec** commented that having a safe harbor is a good thing, but should be agnostic of whether it is in TEFCA.
- **Sasha TerMaat** favored Arien's proposal but suggested there could be an approach to proactively demonstrate that an actor has not been information blocking and include appropriate characteristics. The TEF should not be pointed to though because it is still in flux. There also might be other things that emerge in the future and don't want to eliminate that opportunity.

John Kansky commented that information blocking is intended to prevent information blocking. TEFCA is intended to establish a national interoperability ecosystem. He noted that he is not in favor of establishing TEFCA as a safe harbor.

Steve Lane agreed with John Kansky and felt that information blocking is disjointed from TEFCA. An incentive to participate in TEFCA is good, but this is an odd vehicle to use.

Cynthia Fisher supported what John Kansky noted about a safe harbor. She felt this was alarming and disconcerting from a patient and caregiver perspective.

Andy Truscott felt there were two distinct opinions across the task force and suggested they both should be shared.

Anil Jain suggested that the common agreement needs to reinforce the principles of information blocking. He suggested that the common agreement should align with information blocking, but not giving a safe harbor.

Arien Malec noted that he tried to include these nuances in a recommendation he provided. There should be a single reasonable way to offer data via application programming interfaces (APIs) through permissible purposes that address security and privacy considerations.

Steven Lane noted that ONC says compliance with the terms of the trusted exchange framework if using this as a carrot to get folks to be TEFCA participants that should be said.

Andy Truscott asked the group if there should be a safe harbor that provides assurance.
- **Arien Malec** suggested 'affirmative set of obligations,' rather than 'safe harbor.' He also suggested that there is a lot to comply with regarding information blocking and there is a lot of uncertainty about how to address all of the information blocking requirements.
- **Steven Lane** expressed concerned that just because there is a want for folks to do this, it does not mean that they are not information blocking.
- **Arien Malec** questioned if trusted exchange framework (TEF) wasn't the easy button to comply with 21st Century Cures, why have a TEF?

Arien Malec commented that he doesn't see there is a reason to not implement a safe harbor. If a provider or electronic health vendor (EHR) don't have a playbook to play by, could be in a position that there could be complaints about information blocking behavior. There are no clear grounds to say why not an information blocker. It would be a good thing if there were affirmative obligations, in the absence of other considerations.
- **Steven Lane** noted that it is not a presumption of innocence.
- **John Kansky** commented that he liked the nuance of what Arien was suggesting.
- **Andy Truscott** thought the nuance might be too much for the task force.
- **Denise Webb** noted that this should be tied into the idea that health IT developers who provide these services can then use their participation as an assurance that they will not take any actions that will inhibit the exchange of electronic health information (EHI).
- **Mark Knee** noted that there is a request for information related to the Assurances Condition of Certification.

Arien Malec commented that for providers and EHR vendors there should be an 'easy button' that is a default mode that addresses all of the requirements. This would be addressed by offering certified capabilities and participating in a QHIN. This does not mean other nefarious activities are not occurring, but it provides a target to shoot for.
- **Anil Jain** questioned whether it would be possible to implement and create a best practice and as an industry would be less likely to be information blocking. Those implementing are in a better position to figure this out than to have ONC spell out specific obligations. He felt this added additional certification criteria and was not sure what this accomplishes.
- **John Kansky** commented that he appreciated both sides of the argument. Don't want to add more regulation and be too prescriptive. Is it helpful to think of these affirmative actions as something an organization can do to comply with information blocking? This would be a way to demonstrate that they are not negligent which would give organizations some comfort. If affirmative practices are well chosen, they will move the industry forward.

Andy Truscott commented that the framework is there as a way to enable information sharing. Bad actors will not be able to leverage TEF and comply with the framework while not enabling information sharing. The intent is to enable good actors, rather than a crutch for bad actors to be bad.
- **Steven Lane** commented that he sees value in this, but he thinks it is small and soft. He didn't see this as provided protection or decisive in any charges of information blocking**.**
- **John Kansky** questioned if others feel that this is going to be a difficult regulation to understand and comply with.

- o **Valerie Grey** expressed concern about the complexity of compliance. Small practices will need help. She felt there is help needed for people to understand the kinds of things that are needed to show that they are in compliance.
- **Aaron Miri** noted that there should be a safe harbor to start or a process to slowly implement, similar to how Meaningful Use was implemented.
- **Anil Jain** commented that being too prescriptive can add burden. Having a companion implementation guide or best practices could help, as long as this is not included in the regulatory text.

Andy Truscott asked Mark Knee to highlight ONC's intent.

- **Mark Knee** pointed the task force to the two requests for the information included in the NPRM and reviewed them with the task force.

Sherly Turney agreed with not adding anything more than what is needed. What is in TEF is the basis for how the exchange should occur.

Arien Malec commented that he will defer to the task force. If the task force is worried about regulatory requirements, he would also be worried about what is or isn't information blocking. He would prefer to have a clear set of obligations to comply with versus exceptions. On the positive side, having a positive set of obligations will drive industry in the right direction. Offering an API to patients that meet certification requirements and to make data available for a permissible purpose. He also expressed concern regarding legislative obligations defined through litigation.

Sasha TerMaat noted that during today's conversation the first RFI questions has not been discussed. In much detail. In that regard, she noted that it is not an appropriate framework because the TEF doesn't align.

In regards to the question of whether something could be done proactively, she is supportive of this. Litigation should not be a means for how providers prove this. She would like to encourage the behaviors that are wanted proactively. Information blocking makes things difficult. It is harder to prove that something doesn't happen versus something that does happen. There is an opportunity to proactively discuss activities positively.

The TEF is not necessarily the place to discuss the positive behaviors. Until know what the TEF is, it is premature to link it to information blocking in any particular way. There are certain things that the TEF might be which should be encouraged, but there isn't enough known about the TEF to say there is a link to information blocking.

- **John Kansky** completely agreed with Sasha's statements.
- **Aaron Miri** agreed as well.
- **Denise Webb** noted that Sasha is on point.

Arien Malec questioned if the task force recommendation with ONC is to work with industry to create a voluntary set of obligations.

Andy Truscott noted that there is a lot of sentiment of what TEF is and what it isn't. He suggested detailing this, which could be the start of the recommendation.

Lauren Richie opened the lines for public comment.

Public Comment
There was no public comment.

Comments in the Public Chat

John Kansky: Is it helpful to think of Arien's set of affirmative behaviors as a way for an actor to demonstrate that they are "not negligent" in terms of their compliance with Info Blocking? I.e.. if you do these things you are demonstrating that you are obviously trying to NOT info block

Next Steps and Adjourn

Andy Truscott shared that he would draft what the TEF should be and should not be and will review with Arien Malec and Cynthia Fisher and then bring it back to the task force.

Lauren Richie adjourned the meeting at 12:20 p.m. ET.