

Meeting Notes Health Information Technology Advisory Committee Information Blocking Task Force April 17, 2019, 2:00 p.m. – 3:30 p.m. ET Virtual

The April 17, 2019 meeting of the Information Blocking Task Force (IB) of the Health IT Advisory Committee (HITAC) was called to order at 2:00 p.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

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

Michael Adcock, Co-Chair, Individual Denni McColm, Member, Citizens Memorial Healthcare Lauren Thompson, Member, DoD/VA Interagency Program Office

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.

Welcome

Andrew Truscott, Co-Chair, welcomed the task force members and noted that this meeting represented the final meeting prior to going back to the full committee. He then discussed the agenda and invited the task force members to ask questions or get clarification.

Work Group 1 Output Review

Discussion

- Andrew Truscott highlighted the current definition of health information exchanges (HIE) and health information networks (HIN) and invited the task force members to comment if they were comfortable with the definitions as currently stated.
 - **Cynthia Fisher** sought clarification on what will happen to those entities who name themselves 'information exchanges.' Will these be renamed as 'networks' if they align with the HIN definition?
 - John Kansky addressed Cynthia's question by noting that regardless of the organization's name, if the organization meets the definition of either an HIE or a HIN, then based on the applicable definition, they're considered the category that applies with no need for a change of name.
 - **Cynthia Fisher** noted that her question resulted from a concern that an existing HIE falls out of what the Office of National Coordinator (ONC) currently defines as an exchange and not a network. She further clarified that her concern is that the definition inadvertently is causing a carve-out for an entity that may today be held accountable for an exchange.
 - **Andrew Truscott** asked the task force members if they considered an HIE carve-out based on the new definition to be a likelihood.
 - **John Kansky** reiterated that this concern isn't new, and the definition is purposely broad to keep the scenario Cynthia mentions from happening.
- John Kansky mentioned his concern that the word 'individual' remains in the HIN definition. John went on to say that he expects the task force will be surprised by the organizations deciding that they meet this definition.
 - Andrew Truscott noted that the reference to 'individuals' was a carry-over from the prior wording in the regulations and asked the task force members if there was an inadvertent inclusion.
 - Sheryl Turney concurred with John in that the definitions are very broad, and the task force will be surprised by the organizations deciding that they meet this definition. She went on to provide the example that a HIN could be a clearinghouse to provide the X12 transactions.
- Andrew Truscott asked the task force members if the intent was to include a broad swath of business partners. He went on to cite the HIE definition and asked if an entity is "Accessing, transmitting, processing, handling or other such use of electronic health information (EHI)," an entity is included.

- Steven Lane suggested the intent is to have a very broad definition to encourage data sharing among all stakeholders and asked what is the risk of suggesting ONC throw the net broadly?
- Sheryl Turney answered that currently, vendors are covered under a covered entity. She went on to state that the risk is that some business partners may create their own secondary uses of data and the ability to limit unintended secondary uses may be limited because the vendors are governed by a different agreement such as a master service agreement (MSA) or a vendor agreement. She felt this could result in third parties trying to monetize electronic health information (EHI) data and doubted that patients would want vendors to monetize data without their knowledge and consent. She also noted that this would cause issues with confidentiality agreements.
- Andrew Truscott asked Sheryl if the only way to ensure patient confidentiality wishes is to block information sharing.
- **Sheryl Turney** answered that no, blocking data sharing isn't the goal. The definition of HIN should discuss the types of data sharing that is taking place.
- **Denise Webb** wondered how affiliated versus unaffiliated is defined.
- **Sheryl Turney** believed that the recommended definition as currently stated removes 'affiliated' and this is the cause for her concern.
- Andrew Truscott confirmed that affiliated and unaffiliated are both included and contractual provisions that are causing information blocking are no longer valid as soon as this rule has been enacted.
- Mark Knee responded to a comment mentioned by John Kansky regarding his organization being forced to provide personal health information (PHI) data to the entire populace without compensation. Mark mentioned that the proposed rule states that patients must get free electronic access to their electronic health information. Mark referenced the excluded costs section of the exception for costs reasonably incurred where it states that an excluded fee would be: "(5) A fee based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual's electronic health information."
- **Cynthia Fisher** responded to John Kansky by noting the patient already paid for the data held within HIEs via their plan, deductible, copay, and taxes. Patients cannot have determinants to their health without access to their information.
- **Mark Knee** and **Andrew Truscott** suggested John Kansky, or others concerned, review the exceptions discussed in §§ 171.204 and 171.205.
- **Steven Lane** noted regional HIE's could become the health record bank for anyone in the region, which he felt would be an amazing service. However, he shared his concern that if they cannot charge fees for providing this service, it may hinder investment.
- **Cynthia Fisher** shared her concern for this task force to avoid creating protectionism and instead encourage a free and competitive market to provide access to data.
- Andrew Truscott asked Sheryl Turney if she was recommending the task force include 'affiliated' into the HIN definition.
 - **Sheryl Turney** responded that they didn't know how to define affiliated and suggested there should be a different standard for vendors that are hired to do specific types of work and shouldn't be considered to be a HIN within this definition. She went on to

describe that patient information sharing should be understood and approved by the patient and sees the benefit in the creation of an exception stating that this rule is not intended to apply to relationships for vendors who are already contracted for a specific reason. She expressed concern that some unscrupulous actors or clearinghouses may attempt to monetize data.

- **John Kansky** shared a concern illustrated by an example he shared where application (app) developers, working under the definition as currently written become 'actors' and thus cannot charge patients under the current rules.
- Sasha TerMaat shared, based on John's comment above, her concern that the rule as written could force a business model premised on advertising (since the patient can't be charged) and had concerns for the implications this might cause for the healthcare industry.
- Cynthia Fisher and Sheryl Turney noted that it is currently commonplace for deidentified data to be bought and sold behind the scenes and patients are largely unaware of such practices.

Work Group 2 Output Review

Discussion

- Andrew Truscott redirected the task force to the section within the document discussing parties affected by the information blocking provision. He went on to note that the text outlines that if a developer has a single product certified, then all their products are within scope of the information blocking provision. He also noted that this text has caused concern within the HITAC. Should this task force make a recommendation to ONC that health IT developers as defined for information blocking should not be limited to those developers that have at least one product certified?
 - **Cynthia Fisher** noted that the task force shouldn't seek to include all health IT developers because it would stifle innovation in the marketplace.
 - **John Kansky** agreed with Cynthia's philosophy, however, worried that the verbiage disadvantages certified technology providers if both aren't defined as actors.
 - Sasha TerMaat noted that Cynthia posited that patients could choose whether they valued purchasing certified technology or not; however, she felt the availability of certification criteria for a particular domain that has more influence. She went on to note that there are many domains of health IT that don't have certification criteria and provided examples of scheduling and billing products. Given this, she favored a broad definition of health IT developer that places the same expectations on all actors.
 - **Denise Webb** believes that despite products being uncertified, they should be subject under the same regulations, with the goal of applying fair and evenhanded oversight.
 - **Cynthia Fisher** reiterated her goal of avoiding building systems with unintended consequences of creating protectionism for the status quo. She believes the focus should be on delivering innovation and disruption.
 - Andrew Truscott suggested that the rules should avoid promoting innovation made possible by information blocking, and asked the task force members if expanding the definition of health IT developer to include developers of all health IT would prevent

innovation. He went on to clarify that the suggestion isn't that all health IT be certified but rather for all health IT to comply with information blocking provision and proposals in the proposed rule..

- Denise Webb provided an example of a health system that, for instance, decided they'd use best-of-breed for everything and then chose to move to an integrated platform from a given vendor where some products are certified, and some are not. She then asked what's to protect that provider when they want to get their information out of the uncertified revenue system and the health IT developer is not subject to any information blocking rules? She then reiterated her support for the definition to apply to more than just health IT developers with certified products.
- Andrew Truscott noted that if the task force is considering that the definition allows for a health IT developer, as a developer of all health IT, whether or not it's certified, then there is a gap within the 21st Century Cures Act (Cures) language which doesn't allow sanctions for non-certified health IT developers. If this is the case, they're left with a rule without any enforcement mechanism.
- **Aaron Miri** noted that as a chief information officer (CIO) who purchases products, he builds in contractual language around the data for non-certified products and believes the task force is limited to a recommendation to ONC for updated language.
- **Mark Knee** noted that ONC is bound by the statutory language as currently drafted in the Cures Act.
- Andrew Truscott asked if this task force wanted to make a recommendation that the definition of health IT developer be augmented to include the developers of all health IT whether or not they're certified?
- **Steven Lane** followed up by asking who is going to define what makes a developer a health IT developer?
- **Arien Malec** suggested the task force use the definition for health information technology statutorily defined within the Public Health Service Act.
- Mark Knee read the definition to the task force.
- Andrew Truscott asked the task force to vote on making a recommendation if they would like the definition of health IT developer be augmented to include the developers of all health IT whether or not they're certified, to be more broadly aligned with the definition of 'health IT' within the Public Health Service Act?

Vote Results:

- Andrew Truscott: Abstained
- Cynthia Fisher: Abstained
- o Sheryl Turney: Abstained
- Steven Lane: Supported the change
- Denise Webb: Supported the change
- Sasha TerMaat: Supported the change
- Aaron Miri: Supported the change
- Arien Malec: Supported the change
- Valerie Grey: Supported the change
- John Kansky: Supported the change
- Anil Jain: Unavailable

Andrew Truscott closed by thanking the members for their dedication and noted how much progress has been made.

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 3:30 p.m. ET.