

Meeting Notes

Health Information Technology Advisory Committee

Trusted Exchange Framework and Common Agreement Task Force

June 11, 2019, 12:00 p.m. – 1:30 p.m. ET

Virtual

The June 11, 2019, meeting of the Trusted Exchange Framework and Common Agreement (TEFCA) Taskforce (TF) of the Health IT Advisory Committee (HITAC) was called to order at 12:00 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll.

Roll Call

MEMBERS IN ATTENDANCE

John Kansky, Co-Chair, Indiana Health Information Exchange Cynthia A. Fisher, WaterRev, LLC David McCallie, Jr., Individual Carolyn Petersen, Individual Mark Savage, UCSF Center for Digital Health Innovation Sasha TerMaat, Epic Denise Webb, Individual Noam Arzt, HLN Consulting

MEMBERS NOT IN ATTENDANCE

Arien Malec, Co-Chair, Change Healthcare
Anil Jain, IBM Watson Health
Aaron Miri, The University of Texas at Austin, Dell Medical School, and UT Health Austin
Steve L. Ready, Norton Healthcare
Mark Roche, CMS
Grace Terrell, Envision Genomics, Inc
Andrew Truscott, Accenture
Sheryl Turney, Anthem Blue Cross Blue Shield

FEDERAL REPRESENTATIVE

Laura Conn, Center for Disease Control and Prevention, Federal Representative

ONC STAFF

Zoe Barber, Staff Lead Michael Berry, SME Cassandra Hadley, HITAC Back Up/Support Alex Kontur, SME

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Kathryn Marchesini, Chief Privacy Officer, ONC Lauren Richie, Branch Chief, Coordination, Designated Federal Officer Kim Tavernia, SME

Lauren Richie turned the meeting over to John Kansky, co-chair.

Review Draft Recommendations

John Kansky discussed the plan to review the Draft Transmittal Letter and noted that the current meeting would be used to make corrections and edits directly to the draft letter and the recommendations therein.

- David McCallie asked about the timeframe regarding the draft and the date it needs to be finalized.
 - John Kansky answered that a draft version of the letter must be presented on June 19, 2019, at the next HITAC meeting and the final recommendations are due on July 11, 2019.

John Kansky reviewed sections 2-6 of the letter and then began a discussion of the recommendations within the letter.

2.1 VALUE PROPOSITION AND INFORMATION BLOCKING

Recommendation 1: The TEFCA should express the broad policy aims of enabling better treatment, quality of care, and a more efficient health system.

Recommendation 2: TEFCA rules and requirements should demonstrate alignment with the information blocking rule:

- Key definitions such as Actors and EHI should be the same across both rules; therefore, the
 definitions should be crafted in such a manner as to be rational and effective when applied in
 both the Information Blocking and the TEFCA contexts.
- Participation in the TEFCA should not be a requirement of the Information Blocking regulation, but any enforcement action should give deference to TEFCA participation as a demonstrable and constructive intent against any claim that a provider or health information network knew or should have known that a data exchange practice is likely to or reasonably result in information blocking.

Discussion

- David McCallie stated his support of Recommendation 1 but proposed that Recommendation 2
 be enumerated to include incentives for adoption of the TEFCA. He suggested the inclusion of
 Conditions of Participation that are structured in a way that a provider must be a member of a
 trusted exchange framework (TEF) in order to participate in Medicare. He also stated that
 federal partners, such as the Department of Veteran Affairs (VA), could require providers to join
 a TEF in order to treat VA patients.
- **John Kansky** noted the balance between what participation in a TEFCA ecosystem entails and the incentives that are necessary and asked if there is a concern about enough QHINs coming forward to be QHINs or about participant and participant members signing up.

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- David McCallie responded, noting that there are plenty of possible participants, but it is at the discretion of the entities and whether or not they will continue to function in the same way, or if they will be willing to adopt the TEFCA, and if so, why.
- Sasha TerMaat stated that the participation of a network is voluntary, and as such, the incentives suggested by David McCallie should be aimed toward providers who would sign up with a network. She suggested that this could lead to burden and frustration, where providers feel like they are being evaluated on factors that are out of their control, such as those experienced with Meaningful Use. She cautioned against the addition of a new recommendation in section 2.1.
- Mark Savage stated that, while network participation is voluntary, federal agencies can require
 participation via contract per the Cures Act. He suggested that a recommendation is made to
 ONC to allow each federal agency to require participation via contract.
- **John Kansky** summarized, saying that incentives for participation in TEFCA should be added to Recommendation 1. He also stated that there should be consistency in the language and definitions in the recommendations so that the draft is suitable when applied to all entities.
- **David McCallie** asked the reason for what he perceived as vagueness within the language used in the second bullet of Recommendation 2.
 - John Kansky replied, stating that participating in TEFCA helps to share information, but does not necessarily mean information blocking will not occur. The language in the recommendation is meant to show that being a member of TEFCA does not prevent information blocking.
- **Cynthia Fisher** stated her concern about Recommendation 2. She suggested that the language implies that those participating in TEFCA are not capable of information blocking, which she felt is not the case. She noted that there are indirect information blocking methods that can be utilized while participating in TEFCA.
 - **John Kansky** clarified, saying that participation in TEFCA may be used to mitigate exposure for those that do still information block while participating in TEFCA.
 - Mark Savage stated that the relationship between information blocking and participation in TEFCA in Recommendation 2 should be eliminated. He suggested that engaging in information blocking according to the definitions given should be independent of TEFCA participation.
- David McCallie suggested that the information blocking rule is much broader than what is covered by TEFCA, eliminating the connection between the two. He noted that if participation in TEFCA has no implication on whether one is considered an information blocker, it may disincentivize many providers from participating in TEFCA.
 - John Kansky stated that those who are participating in information blocking need to be accountable. He suggested that those participating in TEFCA are in the spirit of sharing information, rather than blocking it.
- Mark Savage suggested new language for the second bullet of Recommendation 2. He suggested using the phrase "participation in TEFCA is a fact to consider in any claim that a provider or health information network is information blocking" as the opening of the paragraph.
- **Cynthia Fisher** suggested that the phrase "give deference" should be removed from the second bullet of Recommendation 2. She also noted the importance of reflecting on the protections that TEFCA possesses in the form of layers that is not present in other industries.



Denise Webb noted her concern about incentives for participating entities.

2.2 APPLICABLE LAW

Recommendation 3: Covered Entities (CEs) and Business Associates (BAs) that already meet the appropriate obligations should not need to address additional contracting terms unless there are specific additional terms above and beyond Health Insurance Portability and Accountability Act (HIPAA). ONC should clearly state new obligation requirements that may require updates to existing agreements, as well as where meeting existing obligations for CEs and BAs would also meet TEFCA requirements. ONC should develop a process to help map existing contractual terms and conditions to TEFCA terms and conditions.

Discussion

- Noam Arzt stated that the language used in Recommendation 3 should be more concise and direct.
- **David McCallie** asked for clarification from ONC as to where the contractual relationships created by participation in TEFCA surpass existing HIPAA requirements.
- **John Kansky** noted that participation agreements compliant with HIPAA agreements that are acceptable under TEFCA no longer need to be expanded.
- Noam Arzt stated that TEFCA, as proposed, is already beyond HIPAA requirements. He stated
 that the plan for non-covered entities subject to HIPAA privacy and security suggests that TEFCA
 has surpassed HIPAA requirements. He also cautioned that participation agreements that are
 similar in nature do not have the same terms and conditions and suggested that each should be
 scrutinized and treated individually.
 - John Kansky clarified that Recommendation 3 applies only to covered entities and business associates.
 - Zoe Barber noted that TEFCA does go beyond HIPAA regulations for covered entities and business associates as responses to all exchange purposes are required by TEFCA.
- **David McCallie** suggested a clarification in Recommendation 3 be made to explain that going beyond HIPAA regulations is contractual.
- John Kansky suggested that two recommendations be created. He proposed one that states to
 what extent TEFCA can be defined by not requiring regulations beyond those that HIPAA
 requires, and another clarifying that areas going beyond HIPAA regulations are based on
 contracts.
- David McCallie asked that Recommendation 3 seek clarification as to where the Minimum Required Terms and Conditions (MRTC) would elevate requirements beyond those that are currently being matched. He sought to understand where the MRTC goes beyond HIPAA.

Recommendation 4: There is an understanding that existing health information networks (HINs)/health information exchanges (HIEs) will need to amend the terms and conditions in their participation agreements to sign the common agreement (CA) and participate in a QHIN Exchange Network. Those amended terms will flow down and impact Participant and Participant Member agreements as well. In order to minimize the disruption to existing networks, we recommend that ONC employ regulatory tactics aimed at accepting terms and conditions in existing agreements whenever possible. Tactics could include:

• Grandfather clause whereby existing networks already under operation would not need to revise their terms and conditions to avoid disruption to core operations

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- Empower the Recognized Coordinating Entity (RCE) to evaluate and approve a QHIN candidate's
 existing participation agreement, with or without modification. In turn, empower QHINs with
 authority to evaluate and approve existing Participant agreements with support from the RCE
 and process to appeal to the RCE.
- Designating TEFCA terms and conditions as "required" and "addressable."

Discussion

- David McCallie suggested that there would need to be a phased process in order to update
 contracts to uniformity. He asked whether networks where services are missing would be
 excluded from participating in TEFCA, or if allowed they would be required to participate on the
 terms that they would implement the missing services by a certain date.
- **Noam Arzt** commented that the first bullet under Recommendation 4 be removed to give the RCE the responsibility to evaluate the existing participation agreements.
- **David McCallie** commented that the term "bootstrapping" be used instead of "grandfathering" to encourage participation.
- **John Kansky** suggested including the concept of becoming compliant with participation requirements over time as a new bullet under Recommendation 4.
- Noam Arzt noted that the Recommendation 4 paragraph talks about participants, while the second bullet under Recommendation 4 talks about QHINs and sought to be informed of the difference.
 - John Kansky answered, noting that the end of the second bullet aims to extend the same concept to participants. He went on to note that the goal of the recommendation is to recommend tactics to ONC that both promote participation in the TEFCA and give the RCE flexibility to be successful.
- David McCallie suggested that cohorts, grouped based on likeness, have the requirement modified so that they would be able to participate with the understanding that they would later need to meet a set of requirements.

3. DEFINITION, STRUCTURE, AND APPLICATION PROCESS FOR QHINS

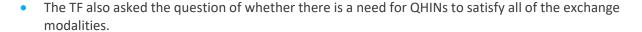
John Kansky asked for suggestions for recommendations for this category; none were given.

4. QHIN TECHNICAL FRAMEWORK (QTF, EXCHANGE MODALITIES, EXCHANGE PURPOSES)

Recommendation 5: The TEFCA should outline functional requirements that are sufficient to meet the policy goals in the TEFCA and not rely too heavily on identifying technical solutions. Put the QHIN functional requirements front and center to communicate the "what" and leave room for flexibility and innovation on the "how."

Recommendation 5a: Given the Broadcast Query described in this draft of TEFCA is not the same
as the generally understood industry term 'broadcast query' (i.e., TEFCA 2 assumes the QHIN or
Participant will employ a record locator service (RLS) to avoid large scale proliferation of queries),
we recommend ONC either drop the distinction of Targeted Query and Broadcast Query or add
explanation of the expected use of an RLS.

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Discussion

- **David McCallie** agreed that participants should not need to satisfy all modalities in order to participate in TEFCA. He suggested the implementation of a minimum set of requirements that all participants must achieve to keep some uniformity and standard. He also made the differentiation between a modality and an exchange purpose.
- John Kansky asked if participants need to fulfill all modalities and exchange purposes.
- Mark Savage stated his concern with giving participants the ability to choose what requirements
 they satisfy and the confusion it could cause. He asked how participants can be fully committed
 without fulfilling the modalities and exchange purposes deemed important for the TEFCA.
 - John Kansky responded, noting that the framework of the TEFCA should be something that
 organizations want to be a part of and see value in, rather than something they need to be
 forced to participate in.
- Mark Savage referred to the Cures Act and its direction for TEFCA, stating that it is more than just a voluntary framework. He noted the ability of participants to choose the requirements to fulfill, which could result in gaps in public need.
 - John Kansky clarified that participants are not allowed to choose which exchange purposes to fulfill and must sign in for all exchange purposes.
 - **Zoe Barber** clarified that responding to all exchange purposes must be supported but initiating an exchange purpose is not required.
- David McCallie suggested that the RCE propose use cases, based upon the exchange purposes, that could be approved and implemented.
- **John Kansky** asked whether the exchange purposes should be used as a starting point or if the exchange purposes should be phased in over time by the RCE.
 - David McCallie responded that exchange purposes would be used in conjunction with use cases. He said that utilizing the use cases in addition to the exchange purposes would allow for a more specific focus and let networks do only the actions that are relevant and productive.
- **David McCallie** suggested removing the terms "broadcast" and "record locator" from Recommendation 5a in an effort to limit confusion. He suggested that the RCE be allowed to determine what technology is necessary.
- **Noam Arzt** stated his strong support of David McCallie's suggestion and suggested that the recommendation describes what should be done rather than how it should be done.
- **Zoe Barber** highlighted that there needed to be clarification on what was meant to be included in the MRTC and the QTF.
 - David McCallie suggested that the technical framework should cover only the basics and allow for the RCE to determine the details on how it will be accomplished.

Public Comment

There were no public comments.

COMMENTS IN THE PUBLIC CHAT FEATURE OF ADOBE

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Mark Savage: Forgot to flag some concern with sentence above, "The TF wishes to note their support for the removal of the Population-Level Query and the narrowing of the Exchange Purposes from Draft 1."

Next Steps and Adjourn

John Kansky stated that the task force intends to have another draft of the document completed by the conclusion of the June 13 meeting.

The meeting was adjourned at 1:30 p.m. ET