

June 11, 2019
Carolyn Petersen, co-chair
Robert Wah, co-chair
Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Robert and Carolyn,

The Health Information Technology Advisory Committee (HITAC) requested that the Trusted Exchange Framework and Common Agreement (TEFCA) Task Force (TF) provide recommendations to the HITAC regarding the proposals in the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. This transmittal offers these recommendations, which are informed by the deliberations among the TF subject matter experts.

1. Background

1.1 Overarching charge: The Trusted Exchange Framework and Common Agreement (TEFCA) Task Force will develop and advance recommendations on the TEFCA Draft 2 to inform the development of the final Common Agreement.

1.2 Detailed charge: Make specific recommendations on the Minimum Required Terms and Conditions (MRTCs) and the Qualified Health Information Network (QHIN) Technical Framework (QTF) —

- » **Broad Goals and Structure:** Recommendations on the value proposition of the TEFCA and alignment with Applicable Law.
- » **Definition, Structure, and Application Process for QHINs:** Recommendations for further clarifying the eligibility requirements and application process for becoming a QHIN.
- » **QHIN Technical Framework, Exchange Purposes and Modalities:** Recommendations on the overall functional requirements in the QTF. Recommendations on enhancing or clarifying the seven (7) exchange purposes and three (3) exchange modalities proposed in the MRTCs, as well as provisions regarding EHI reciprocity and permitted and future uses of EHI.
- » **Privacy:** Recommendations on privacy requirements for participating entities, including Meaningful Choice, Written Privacy Summary, Summary of Disclosures, and Breach Notifications
- » **Security:** Recommendations on security requirements for participating entities, including minimum security requirements, identity proofing, authorization, and authentication.

2. Overarching Recommendations

2.1 Value Proposition and Interoperability and Information Blocking

As part of our deliberations, the TEFCAs TF discussed the overall value and purpose of the TEFCAs, the incentives for participation, and what a successful TEFCAs would look like. The TF also looked at the TEFCAs in relation to the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program rule (Interoperability Rule) and framed two possible policy goals for consideration. The first, more narrow view asked whether the proposed TEFCAs would address the means and needs of Congress, i.e. would it result in an optimal path to “full network to network exchange of health information?” The second, broader view asked whether the TEFCAs as drafted expresses the broader policy aims and goals of improved care, improved health and reduced cost, and also, does it serve to reduce the prevalence and probability of information blocking (without representing a safe harbor)?

Recommendation 1: The TEFCAs should express the broad policy aims of enabling better treatment, quality of care, and a more efficient health system. The TEFCAs can only meaningfully advance these aims if it is:

- Carefully crafted to balance the addition of new requirements with complementing/coexisting with existing frameworks and networks, and
- Appropriately adopted by the stakeholders of health and healthcare which must exchange information.

We therefore recommend significant attention to both these key issues:

Complementing existing frameworks and networks – Consistent with the 21st Century Cures Act, TEFCAs will best accomplish the above policy aims if its goal is broad, appropriate, secure, and seamless or low-friction exchange of health information – with individuals and across the healthcare system. The TF believes it is important to view and leverage existing frameworks and networks as assets in achieving that aim and urges ONC to craft TEFCAs with that view. In general, this implies that whenever possible, without compromising the goals of TEFCAs, the disruptive impact on existing frameworks and networks should be minimized.

Adoption of TEFCAs –The second draft of TEFCAs manifests that ONC has clearly listened and responded to feedback. The more the final TEFCAs is artfully balanced to achieve its ends in a way that stakeholders can accommodate, the more it will be organically adopted. The TF urges consideration of this perspective as ONC weighs new feedback and considers options and compromises. Regardless of how well-conceived the final TEFCAs is, it will be necessary to ensure there are sufficient incentives to encourage participation. The opportunity for both “carrots and sticks” appears to exist including:

- Education and outreach across the industry
- Outreach to existing frameworks and networks to coordinate launch and adoption efforts
- Funding aimed at any emerging financial obstacles for QHINs and participants
- Federal agencies requiring TEFCAs participation as a condition of contracts with federal agencies
- CMS requiring TEFCAs participation as a condition of participation in Medicare and Medicaid

Recommendation 2: ONC should align TEFCA rules and requirements with the Interoperability 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 Interoperability Rule and the TEFCA contexts.
- Active, good-faith participation in exchange provided through the TEFCA should address information blocking requirements relevant to cross network exchange purposes, uses and modalities provided through TEFCA.
- Because TEFCA only addresses a portion of information exchange activities relevant to information blocking, TEFCA participation alone should not be made a formal exception to information blocking or create a safe harbor
- Participation in TEFCA should not be a condition of certification or requirement for information blocking requirements. It should, however, be the easiest and most direct path to address relevant requirements.
- We believe that a careful balance needs to be struck in order to encourage participation in the TEFCA, while not inadvertently providing bad actors with an opportunity to circumvent regulation compliance.
- [Placeholder for specific recommendation(s) related to the API requirements for 2015 Edition Certification after further discussion]

2.2 Applicable Law

As part of our overarching discussions, the TEFCA TF discussed Applicable Law as it relates to the TEFCA and boundary conditions for when and to whom Applicable Law applies. The TF perceives some lack of clarity specific to HIPAA obligations on Covered Entities (CEs) and Business Associates (BAs) and when and how TEFCA creates new and additional obligations.

Recommendation 3a: Whenever possible, align TEFCA privacy and security obligations with HIPAA privacy and security obligations. While it is understood that new Exchange Purposes create uses beyond HIPAA-defined Treatment, Payment, and Operations, and EHI expands the relevant data beyond PHI, alignment of privacy and security obligations will minimize the impact on Covered Entities (CEs) and Business Associates (BAs) and increase the probability that they will adopt TEFCA.

Recommendation 3b: To add clarity and avoid misinterpretation, ONC should clearly identify new obligations beyond HIPAA that may require updates to existing operations, policies, and agreements, as well as stating where meeting existing obligations for CE and BAs would also meet TEFCA requirements. ONC should develop a mapping process to help map existing HIPAA terms and conditions to TEFCA terms and conditions.

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 CA and participate in the QHIN Exchange Network, and that 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 MRTCs be addressable through terms and conditions in existing agreements whenever possible through such means as:

- Allowing the RCE (with respect to QHINs) and QHINs (with respect to Participants) the latitude to agree to time-limited “bootstrap” periods whereby existing networks already under

operation would be able to participate in TEFCAs while having a defined, agreed upon period of time to revise their terms and conditions to avoid disruption to their participant network and existing information exchange. With respect to the RCE-QHIN relationship, the RCE may be able to employ this concept by grouping cohorts appropriately based on their bootstrap period/agreement.

- Allow the RCE to evaluate and approve a QHIN candidate's existing participation agreement or relevant terms of that agreement, with or without modification as meeting the requirements of the MRTCs. In turn, allow QHINs, with the support of the RCE under a clear governance process established by the RCE, to evaluate and approve existing Participant agreements or relevant terms of those agreements.
- Designating TEFCAs terms and conditions as "required" and "addressable"

3. Definition, Structure, and Application Process for QHINs

The TF supports ONC's proposal on the definition, structure, and application process for QHINs in TEFCAs Draft 2 with no further edits.

4. QHIN Technical Framework (QTF, Exchange Modalities, Exchange Purposes)

The TEFCAs TF discussed the proposed exchange purposes and modalities in the TEFCAs and whether Draft 2 contains the right bundling of purposes and modalities. The TF deliberated the definitions of the exchange modalities and the functional requirements in the MRTCs, and discussed whether the technical and functional requirements in the QTF are responsive to the policy goals in the MRTCs. In general, the TF believes that ONC should focus on specifying policy and functional requirements and defer technical solutions to the RCE.

The TF notes that there are inconsistencies between the diagrams in the QTF and the definitions and functional requirements in the MRTCs.

Recommendation 5: In the released version of the TEFCAs, ONC should align all descriptions and diagrams to the functional requirements outlined in the MRTCs; RCEs, QHINs and the ONC should ensure that the QTF technical requirements address the functional requirements, and should ensure that technical requirements do not accidentally turn into functional requirements.

Further, the TF believes that there is a contradiction between the requirements for a query response in the information blocking section of the Interoperability Rule and the MRTCs. The Interoperability Rule assumes that all EHI is being exchanged, whereas the MRTCs require that participating entities respond (at a minimum) with the EHI in the USCDI that they have available. **[Possible recommendation here]**

Recommendation 6: ONC should explicitly address the gap between information blocking requirements and TEFCAs requirements for cross network exchange. For example, when a requestor desires additional EHI not currently part of the USCDI, it is the requestor's responsibility to make that request directly to the information source, outside of the process established by the TEFCAs.

Recommendation 7: The TECCA should outline functional requirements that are sufficient to meet the policy goals in the TECCA and avoid whenever possible identifying specific technical solutions. The QHIN functional requirements should be put front and center to communicate the “what” and leave room for flexibility and innovation on the “how”. In general, the QTF should be minimized in favor of giving the RCE authority to work out flexible and evolving technical approaches with the QHIN Exchange Network.

The TF discussed the terms QHIN Targeted Query and QHIN Broadcast Query described in the second draft of the TECCA. Our understanding of these terms as described is not the same as the generally understood industry terms “targeted query” and “broadcast query”. As an example, our understanding is that the TECCA 2 functionally requires the QHIN to identify Participants, Participant Members, and relevant data, through means which might including a document repository or a record locator service [RLS] to avoid large scale proliferation of queries. The industry term, by contrast, implies targeted query to a single setting of care, and broadcast query to many settings of care. Reuse of definitions in a different context will cause confusion

Recommendation 8: We recommend ONC avoid the use of the term Targeted Query, Broadcast Query (or RLS) and instead offer a clear functional description of QHIN query response obligations.

The TF discussed the current requirement for QHINs to satisfy all of the exchange modalities. While there is some elegance to the concept of a “single on-ramp”, different exchange modalities require different capabilities and specialties. For example, a public health reporting organization may wish to form a QHIN to address state by state needs for reportable labs, reportable conditionals, and other disease surveillance needs. Such a QHIN would need only a subset of exchange modalities and permitted uses.

Recommendation 9a: [Requires more discussion] As currently stated in the TECCA ONC and the RCE should require QHINs to serve all defined exchange Modalities and Purposes.

Recommendation 9b: [Requires more discussion] ONC and the RCE should allow and support “specialized QHINs” to serve a subset of Exchange Modalities and Purposes?

4.1 Individual Access Services (IAS)

The TF explored the definition and functional requirements of the Individual Access Services (IAS) Exchange Purpose. The TF strongly endorses the requirement for IAS, as well as the expansion of the HIPAA right to include all participating entities and all EHI. However, the TF notes that IAS is constrained to only two rights under HIPAA, 45 CFR 164.524—accessing and obtaining a copy of EHI and sending to a 3rd party. The TF discussed many other core use cases that are valuable for patients but not included in the definition of IAS, including shared care planning, a patient’s right to submit corrections and amendments to their records under the HIPAA privacy rule, patient-generated health data (PGHD), patient-reported outcomes, remote monitoring, and the Precision Medicine Initiative. The TF was split on whether the IAS Exchange Purpose in the TECCA should be expanded to include the full spectrum of individual needs up front, or whether such capabilities should be phased in by the RCE.

Recommendation 10a: ONC should expand the IAS Exchange Purpose immediately to build in broader functionality for individuals that is not limited to obtaining and accessing a copy of their EHI, and sending to a 3rd party. At a minimum IAS should include the right for an individual to request an

amendment to their EHI, as defined in HIPAA 45 CFR 164.526. Additional use cases to incorporate may include:

- The ability for providers, patients, and payers to participate in shared care planning and to share and retrieve a patient's dynamic shared care plan for purposes of coordinating care.
- EHI that is created by or recorded by the patient i.e. PGHD, patient-reported outcomes, and remote monitoring.
- The Precision Medicine Initiative led by the National Institutes of Health (NIH) that allows patients to access their health information, as well as research that uses their data to more accurately predict treatment and prevention strategies for specific patient populations.

Recommendation 10b: ONC should start with IAS Exchange Purposes that are mature locally and scale nationally through the TEFCA. ONC should work with stakeholders to develop and test additional forms of individual exchange (including amending, shared care planning and data donation for research) and work with the RCE and QHINs to scale those forms of exchange over time as those forms mature.

The TF also discussed various scenarios for who is required to respond to queries for IAS and the definition of Direct Relationship. Specifically, the TF discussed the requirement, as currently drafted in the MRTCs, for public health agencies to respond to IAS and noted an inconsistency in the Draft MRTCs regarding whether all participating entities must respond to requests or only those with a Direct Relationship with the individual who is the subject of the information.

Recommendation 11: ONC should clarify whether all participating entities must respond to requests for IAS or only those with a Direct Relationship to the individual. ONC should further clarify the meaning of the term Direct Relationship. The MRTCs uses this term variously to refer to an individual's designated Participant(s)/Participant Member(s) that are allowed to initiate queries on the individual's behalf, and the relationships to recipients of such queries. For purposes of clarity, ONC should define a clear term (one that does not overlap with existing legal terms regarding treatment relationships), such as Individual Designated Participant/Participant Member, to cover the former definition.

For the latter definition, ONC should include relationships defined by Applicable Law in the definition. Further, the definition of Direct Relationship should detail the types of services that must be offered in order to establish a Direct Relationship.

Recommendation 11a: [Requires more discussion] ONC should not require all public health agencies to respond to IAS, particularly those that primarily exist for disease surveillance and do not maintain patient-centered data, except when it is required by Applicable Law (such as when a public health agency is acting as a CE under the HIPAA rules). However, where the capability exists or in cases where bi-directional exchange is currently happening (e.g. immunization registries), the TF does not wish to discourage such reciprocity from occurring even if different standards than those incorporated in the QTF are used.

5. Privacy

5.1 Meaningful Choice

The TEFCA TF discussed the Meaningful Choice policy in the MRTCs, including its scope and intent. We note that Meaningful Choice, as drafted, is all or nothing and does not allow for exceptions for things

like emergency treatment or more granular consent. There is concern that, as drafted, this is an underspecified set of requirements with many complications. Currently, sharing the privacy preferences of an Individual's meaningful choice action across a network is not a very well solved technical problem. Today, in general, once providers have incorporated data from the outside world into their EHRs, the expectation is they will keep that as the legal part of the record because they will have used it to make treatment decisions.

The TF also discussed the original intent of Meaningful Choice as a concept. The notion of Meaningful Choice was introduced to move away from the notion of opt-in and opt-out as the only two options. Opt-in and opt-out can be implemented in ways that fail to permit the patient to give meaningful consent. Rather, meaningful consent occurs when the patient makes an informed decision and the choice is properly recorded and maintained.

Recommendation 12: ONC should clarify the policy goals around Meaningful Choice and leave the granular technical requirements to the RCE. Policy goals should ensure that Meaningful Choice is not just a “check-the-box” exercise, but that it provides meaningful information and opportunity for discussion about where and how an individual’s EHI will be used and disclosed. Consent should be meaningful in that it does the following:¹

- Allows the individual advanced knowledge/time to make a decision. (E.g., outside of the urgent need for care.)
- Is not compelled, or is not used for discriminatory purposes. (E.g., consent to participate in a centralized HIO model or a federated HIO model is not a condition of receiving necessary medical services.)
- Provides full transparency and education. (I.e., the individual gets a clear explanation of the choice and its consequences, in consumer-friendly language that is conspicuous at the decision-making moment.)
- Is commensurate with the circumstances. (I.e., the more sensitive, personally exposing, or inscrutable the activity, the more specific the consent mechanism. Activities that depart significantly from a patient’s reasonable expectations require greater degree of education, time to make decision, opportunity to discuss with his/her provider, etc.)
- Must be consistent with reasonable patient expectations for privacy, health, and safety; and
- Must be revocable. (i.e., patients should have the ability to change their consent preferences at any time. It should be clearly explained whether such changes can apply retroactively to data copies already exchanged, or whether they apply only "going forward.")

Furthermore, the TF discussed the meaning of “prospective” as it relates to Meaningful Choice. As drafted, an individual’s Meaningful Choice must be respected on a prospective basis, but any EHI that has been used or disclosed prior to the Individual’s exercise of Meaningful Choice may continue to be used or disclosed. While we understand ONC’s intent for allowing the use and disclosure of EHI that has already been shared prior to the exercise of Meaningful Choice, some members of the TF believe that this is problematic. The TF acknowledges the practical realities of deleting the EHI once it has been incorporated into the patient records, but some members advocate for a recommendation that the EHI no longer be used or disclosed after an individual’s exercise of Meaningful Choice.

¹Health IT Policy Committee, Privacy & Security Tiger Team. September 1, 2010. https://www.healthit.gov/sites/default/files/hitpc_transmittal_p_s_tt_9_1_10.pdf

Recommendation 13: [Requires more discussion] ONC, in the MRTCs, should *not* allow for the use and disclosure of individuals' previously-disclosed EHI following an individual's exercise of Meaningful Choice.

Recommendation 14: [Requires more discussion] ONC should clarify the extent of Meaningful Choice and how Meaningful Choice will be communicated. Specifically:

1. Will Meaningful Choice only apply to an individual's information exchanged for defined Exchange Purposes within the TEFCA, or is Meaningful Choice expected to apply more broadly to govern the sharing of the individual's information outside the TEFCA ecosystem?
2. Once exercised by an individual, their Meaningful Choice is expected to be communicated "up" their QHIN branch and shared by their QHIN with the other QHINs. Which organizations in the TEFCA ecosystem are expected to be aware of that individual's MC and respect it? Only the organization with the Direct Relationship, all Participants or Participant Members under QHIN branch where the individual has a Direct Relationship, or all QHINs, Participants, and Participant Members across the TEFCA ecosystem?

Respectfully submitted,

Arien Malec and John Kansky
TEFCA TF Co-Chairs