



The Office of the National Coordinator for
Health Information Technology
Health IT Advisory Committee

Trusted Exchange Framework and Common Agreement (TEFCA) Task Force: Draft Recommendations to the HITAC

Arien Malec, Co-Chair
John Kansky, Co-Chair

June 19, 2019



Agenda

- Task Force Members
- Task Force Charge
- Review draft recommendations
- Questions and Feedback

Membership

Membership	Organization	Role
Arien Malec	Change Healthcare	Co-Chair
John Kansky	Indiana Health Information Exchange	Co-Chair
Andrew Truscott	Accenture LLP	HITAC Committee Member
Anil Jan	IBM Watson	HITAC Committee Member
Carolyn Petersen	Individual	HITAC Committee Member
Aaron Miri	University of TX, Austin Dell Medical School & UT Health Austin	HITAC Committee Member
Denise Webb	Individual	HITAC Committee Member
Sheryl Turney	Anthem Blue Cross Blue Shield	HITAC Committee Member
Sasha TerMaat	Epic	HITAC Committee Member
Steve Ready	Norton HealthCare	HITAC Committee Member
Cynthia Fisher	WaterRev, LLC	HITAC Committee Member
Mark Roche	CMS	HITAC Committee Member
David McCallie	Individual	Public Member
Mark Savage	UC San Francisco	Public Member
Noam Artz	HLN Consulting	Public Member
Grace Terrell	Envision Genomics	Public Member
Zoe Barber	ONC	ONC Staff Lead
Kimberly Tavernia	ONC	ONC Co-Lead
Michael Berry	ONC	SME, RCE
Alex Kontur	ONC	SME, Technical
Morris Landau	ONC	SME, HIPAA and Privacy/Security

Task Force Charge

- **Overarching charge:** The Trusted Exchange Framework and Common Agreement (TEFCA) Task Force will develop and advance recommendations on the TEFCA Draft 2 to inform development of the final Common Agreement.
- **Detailed charge:** Make specific recommendations on the Minimum Required Terms and Conditions and the Qualified Health Information Network (QHIN) Technical Framework (QTF) —
 - » **Overarching Recommendations:** Recommendations on the value proposition of the TEFCA and alignment with Information Blocking and Applicable Law.
 - » **Definition, Structure, and Application Process for QHINs:** Recommendations for further clarifying the eligibility requirements and application process for becoming a QHIN.
 - » **Exchange Purposes and Modalities:** 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.



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Overarching Recommendations



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Overarching Recommendations: Value Proposition

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

Overarching Recommendations: Applicable Law

- **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 CEs 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.

Overarching Recommendations: Applicable Law

- **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 TEFCA 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 TEFCA terms and conditions as “required” and “addressable”



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QHIN Technical Framework (QTF), Exchange Purposes, & Exchange Modalities



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QTF, Exchange Modalities, & Exchange Purposes

- **Recommendation 5:** In the released version of the TEFCA, 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.
- **Recommendation 6:** ONC should explicitly address the gap between information blocking requirements and TEFCA 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 TEFCA.

QTF, Exchange Modalities, & Exchange Purposes

- **Recommendation 7:** The TEFCA should outline functional requirements that are sufficient to meet the policy goals in the TEFCA 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.
- **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.

QTF, Exchange Modalities, & Exchange Purposes

- **Recommendation 9a:** [Requires more discussion] As currently stated in the TEFCA, 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?

Individual Access Services

- **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.

Individual Access Services

- **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 MRTC 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.
- **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.



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Privacy



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Privacy: Meaningful Choice

- **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:
 - » 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.")

Privacy: Meaningful Choice

- **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:
 - » 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?
 - » 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?



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