



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

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

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

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Agenda

- Task Force Members
- Task Force Charge
- Present Final 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 Jain	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
David McCallie	Individual	Public Member
Mark Savage	UC San Francisco	Public Member
Noam Arzt	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 the ONC Interoperability Rule 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 that must exchange information.

We recommend that ONC consider both “carrots and sticks” for TEFCA adoption, such as:

- 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
- CMS encouraging TEFCA participation
- Federal agencies requiring TEFCA participation as a condition of contracts with federal agencies

Overarching Recommendations: Interoperability Rule

Recommendation 2: ONC should align TEFCA with the ONC Interoperability Rule:

- Key definitions such as HIE, HIN, and EHI should be the same across both rules.
- Active, good-faith participation in exchange provided through the TEFCA should address and be evidence for compliance with 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 maintenance and certification requirements for the information blocking condition as suggested in the ONC's proposed rule. It should however, be an easy and direct path to address relevant requirements.

Recommendation 3: ONC should move forward with the requirement for data to be included in a query response as proposed in Draft 2, at a minimum, with the subset of EHI specified in the USCDI if the respondent has the data available, and focus on rapid yet prudent expansion of the USCDI standard.

Overarching Recommendations: Applicable Law

Recommendation 4: To add clarity and avoid misinterpretation, ONC should categorize Privacy and Security obligations as:

- HIPAA obligations extended to cover Participants and Participant Members who are not CEs or BAs.
- New privacy and security obligations which go beyond HIPAA and cover all Participants and Participant Members, such as:
 - » Meaningful Choice
 - » No EHI Outside the US
 - » Specific identity-proofing and authentication policies (IAL2 and AAL2).

Overarching Recommendations: Applicable Law

Recommendation 5: To comply with MRTCs, existing HINs/HIEs will likely need to amend the terms and conditions in their participation agreements to enter into and sign the Common Agreement and participate in the QHIN Exchange Network, and those amended terms will flow down and impact Participant and Participant Member agreements as well for TEFCA-related activities. In order to minimize the disruption to existing networks, we recommend the MRTCs be addressable through terms and conditions in existing agreements whenever possible through such means as:

- Allowing 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.”
- When changes to existing agreements are required, allowing Participants and QHINs to participate in TEFCA while having a defined 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 appropriately grouping cohorts based on their bootstrap period/agreement.



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



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QTF, Exchange Modalities, & Exchange Purposes

Recommendation 6: The TEFCA should outline functional requirements 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.” Because the RCE and initial QHINs are presumed to have familiarity with exchange standards and approaches, we recommend the ONC remove the QTF, and clearly document functional requirements (perhaps in a QHIN Functional Framework (QFF)). Given the QTF was created as initial guidance for the RCE, which has authority to work out flexible and evolving technical approaches with the QHIN Exchange Network, we recommend the RCE be provided the comments and feedback the ONC received in the comment period. We recommend it be clear the RCE is free to choose any technical enablement(s) of the functional requirements listed in the QFF.

Recommendation 7: We recommend the ONC focus on the functional requirements for QHIN query response, and avoid using the terms Targeted Query and Broadcast Query (or Record Locator Service), which have multiple interpretations/meanings.

QTF, Exchange Modalities, & Exchange Purposes

Recommendation 8: All QHINs should serve a floor set of functional requirements, Exchange Purposes and modalities. Participants and Participant Members should be able to serve (and respond to) a subset of Exchange Purposes and modalities that are appropriate to their scenario of usage, constrained as appropriate by the needs of individuals as well as the goal of reciprocity.

Recommendation 9: ONC should clarify the role of the TEFCA relative to other nationwide exchanges served through parallel trust frameworks. In particular, ONC should clarify the intended uses of Message Delivery relative to other uses of network activities that send messages.

Individual Access Services

Common Recommendation 10: ONC should place the needs of individuals front and center in the TEFCA, and those needs will certainly be broader than exercising the HIPAA right to access over time. In addition, ONC should clarify the functional requirements for individual access, keeping in mind typical access patterns (for example, health app integration on a mobile device).

Alternative 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 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.

Alternative Recommendation 10b: ONC should establish a policy framework to get to broader individual services, including amendment, shared care planning, PGHD and data donation for research with a clear timetable. ONC and the RCE should roll out individual services that are ready for large scale adoption, starting immediately with IAS Exchange Purposes as described in Draft 2 as this constitutes a significant step forward for patient access. ONC should work with the RCEs and QHINs to develop and test the additional forms of individual exchange within the timeline established for the expanded usage.

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.

Recommendation 12: 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.

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.

Individual Access Services

Recommendation 13: ONC should not require all public health agencies to respond to query, including IAS, particularly those that primarily exist for disease surveillance and do not maintain a longitudinal patient record, except when it is required by Applicable Law (such as when a public health agency is acting as a CE under the HIPAA rules).



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Privacy



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Privacy: Meaningful Choice

Recommendation 14: ONC should clarify the language and policy goals around Meaningful Choice and leave the granular technical requirements to the RCE. The TF recommends clearer definition of “Meaningful Choice” and its scope, to express (a) ONC’s intent that, by default, Individuals’ EHI is used and disclosed in exchanges under TEFCA unless the Individual exercises a Meaningful Choice to disallow any further, prospective Use and Disclosure, and (b) that, like TEFCA, the Individual’s Meaningful Choice only applies to revoke prospective Use and Disclosure in exchanges within TEFCA but not use and disclosure of EHI outside of TEFCA. 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: (Note: The current definition of Meaningful Choice already captures the first, second, and sixth bullets below, but we include them here to complete the list.)

- Allows the individual advanced knowledge/time to make a decision. (e.g., outside of the urgent need for care.)
- Is not compelled, and 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 EHI, the more specific the consent mechanism. Activities that depart significantly from a patient’s reasonable expectations require greater degree of education, more time to make a decision, additional 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 revoke their Meaningful Choice and resume use and disclosure of their EHI under TEFCA 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 15: It is reasonable and practical to permit the use and disclosure of an individual's previously-disclosed EHI following an individual's exercise of Meaningful Choice to not have their EHI shared through the TEFCA in light of the significant challenge created in contemplating how to implement applying such a policy retrospectively.

There was a very strongly held minority opinion that the TEFCA should expand the scope of Meaningful Choice to include restrictions on re-disclosure of exchanged information that has been obtained via the QHIN Network.

Recommendation 16: As drafted, once an individual exercises his or her Meaningful Choice to not have his or her EHI used and disclosed via the TEFCA, TEFCA 2 constrains the prospective use and disclosure of an individual's data to Exchange Purposes whereas prior to the exercise of Meaningful Choice, the use and disclosure was defined by Section 2.2.2 of the MRTCs. To avoid introducing unnecessary complexity, the TF recommends that the prospective use and disclosure of an individual's information after the exercise of Meaningful Choice continue to be defined and constrained by Section 2.2.2 and not the narrower Exchange Purposes only.

Privacy: Meaningful Choice

Recommendation 17: ONC should clarify how broadly an expressed Meaningful Choice will be applied. Specifically, once exercised by an individual, the Meaningful Choice is expected to be communicated “up” the QHIN branch and shared by the QHIN with the other QHINs. Clarify which organizations in the TEFCA ecosystem are expected to be aware of that individual's Meaningful Choice and respect it. Also, clarify whether it is 1) only the organization with the Direct Relationship, 2) all Participants or Participant Members under that QHIN branch where the individual has a Direct Relationship, or 3) all QHINs, Participants, and Participant Members across the TEFCA ecosystem.

Privacy: Summary of Disclosures and Auditable Events

Recommendation 18: ONC should align requirements around auditable events and summary of Disclosures. The MRTCs should describe the policy requirements for audit retention, including what's required to be audited and how long it should be maintained, in the MRTCs and not delegate to the QTF. ONC should move the six-year retention requirement to the audit language.

Recommendation 19: The MRTCs should require a summary of disclosures only from the entity with the Direct Relationship to the requesting Individual (and the associated QHIN). Such a summary should include disclosures when data have been pulled from the associated QHIN and disclosures when data have been requested by the associated QHIN.



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Security



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Security: No EHI Outside the US

Recommendation 20: ONC should focus on the need for risk-based security assessment and remediation for QHINs, and not make “where the data reside” the central criterion for security.

Recommendation 21: In order to clarify governing law, the restriction to have QHINs maintain data center operations and data at rest in the US is reasonable. ONC should define these requirements in terms of operations and data at rest, and not use the term “cloud services,” which excludes on premise data center services.

Recommendation 22: Because of the need to have data follow the patient and because of the existence of international settings of care (e.g., Department of Defense Military Treatment Facilities), ONC should not restrict data access and exchange to US national boundaries and permit international data access and exchange.

Security: Controlled Unclassified Information (CUI)

Recommendation 23: The TF recommends that ONC remove the section related to CUI.

Recommendation 24: The TF recommends that ONC make it clear that the additional obligations on CUI handling or other specific requirements will be borne by Federal partners. As Federal partners onboard to TEFCA-administered exchange, ONC should work with Federal partners to ensure additional security requirements do not impede the principle of reciprocity.

Security: Privacy/Security Labeling

Recommendation 25: ONC should add Privacy/Security labeling to the TEFCA only via a common standards and policy framework that is implemented in provider workflow systems. As the HITAC recommended previously to ONC, there would be value to this proposal but more work is required to make labeling implementable. In particular, there should be accompanying policy guidance for how to handle labeled data. In particular, the policy framework should address when labelled data can and cannot be used, and how duplicate data that is labelled and un-labelled should be handled.

Security: Certificate Authority, ID Proofing, Authentication

Recommendation 26: The TF believes the ONC should not include Certificate Authority (CA) services as part of the MRTCs. The TF notes the requirements to be a trusted CA go far beyond the proposed MRTC terms and should be considered out of scope for TEFCA.

We recommend that ONC delete this provision.

Recommendation 27: For purposes of clarity, the TF recommends the ONC overtly state that QHINs can accept the identity proofing of Participants and Participant Members under its QHIN branch on the basis that all Participants and Participant Members have agreed to flow-down agreement terms specifying the same identity proofing standards as in the Common Agreement.

Recommendation 28: We agree with ONC's inclusion of AAL2 and IAL2. We recommend the ONC allow appropriate time for industry to accommodate these requirements.



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