June 13, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
330 C ST SW
Mary Switzer Building; Mail Stop 7033A
Washington, D.C. 20201

Re: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Submitted electronically

Dear Doctor Rucker:

The Sequoia Project is pleased to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.* We appreciate ONC's demonstrated commitment to consider thoughtfully the comments that it receives from stakeholders in response to this draft document.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances interoperability for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth Exchange and Carequality now operate under their own non-profit corporations.

The Sequoia Project currently supports the RSNA Image Share Validation Program, the Patient Unified Lookup System for Emergencies (PULSE) and Interoperability Matters. Our comments are based on our organization's significant experience supporting large-scale, nationwide health data sharing initiatives, including assessments of interoperability and security capability of exchange participants. Through these efforts, we serve as an experienced, transparent and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability, including in-depth development and implementation of trust frameworks and associated agreements. This work extends to several crosscutting projects, including patient matching, improving the quality of exchanged clinical documents, information blocking, and other matters prioritized by stakeholders, such as health IT disaster response.

Our deep experience implementing national-level health IT interoperability, including our track record of supporting and operationalizing federal government and private sector interoperability initiatives, provide a unique perspective on the draft TEFCA.

We know through our own experience that seamless nationwide sharing of health information is most readily enabled through trust agreements, consistent policy and technical requirements, and appropriately balanced governance to provide assurance of trust and interoperability. This experience has proven that an interoperable health information technology ecosystem is best supported through public-private collaboration, grounded in practical implementation that advances interoperable health information sharing and engenders public trust. In addition, we have learned that the solid foundation of a trust agreement can support an evolving set of use cases without having to routinely change the underpinning of the legal framework.

In this letter, we provide priority high-level and detailed comments intended to help ONC further refine this second draft of the TEFCA. We share an overall aim to improve the health and health care of patients and our nation through more seamless and secure patient, provider and other appropriate stakeholder access to and use of health information.

Overview of The Sequoia Project's Comments

The Sequoia Project supports the congressional intent of the 21st Century Cures (Cures) legislation for greater data liquidity and the potential role of a "trusted exchange framework" as envisioned in that legislation. We appreciate the ways in which ONC has approached development of the Trusted Exchange Framework and Common Agreement (TEFCA) and its multiple requests for stakeholder input. Our detailed comments are in the attached Appendix. Overall:

- We appreciate the changes ONC made from Draft 1 summarized in the chart on page 20 of the TEFCA Draft 2.

- We urge ONC to be very mindful of the congressional intent that the TEFCA avoid disruption and duplication of "existing exchanges between participants of health information networks". In our view, as currently drafted, the TEFCA would both disrupt and duplicate existing exchange mechanisms and would require extensive changes to existing activities and revisions to the terms of thousands of legal agreements. We urge ONC to look for every opportunity to minimize or eliminate such duplication and disruption, especially in the need to revise legal agreements that have, in many cases, taken years to be developed and executed in support of large-scale information sharing.

- The TEFCA should address real, material gaps in current exchange networks, frameworks and agreements. One area where we believe that the TEFCA can add real value is harmonization of agreed upon purposes for exchange and use of information.

- We support ONC's goals for the TEFCA: (1) a single "on-ramp" to nationwide connectivity; (2) enable Electronic Health Information (EHI) to securely follow the patient when and where it is needed; and (3) support nationwide scalability.

- We note that the Carequality trust framework is designed to provide a single on-ramp and to reduce the extent to which "health systems and providers . . . must join multiple networks that do not connect with one another in order to receive the information they need to care for their patients."

- We support the responsibility for the Recognized Coordinating Entity (RCE) to develop the Additional Required Terms and Conditions (ARTCs), subject to ONC approval. At the same time, because the ARTCs must be consistent with and not revise the Minimum Required Terms and Conditions (MRTCs), we believe that the RCE should also have an important role in finalizing the MRTCs in conjunction with ONC. For both tasks, the RCE should also be able to engage with prospective QHINs, Participants, and Participant Members.

- We strongly support the proposal that, in a shift from TEFCA Draft 1, the Qualified Health Information Network (QHIN) Technical Framework (QTF) would be incorporated by reference in the Common Agreement (CA) and finalized by the RCE.

- We agree with the proposed role of and selection criteria for an experienced private sector RCE to implement and monitor compliance with the Common Agreement as well as the definition of "affiliated entity" in a companion ONC FAQ. We also believe that the final TEFCA and the associated RCE cooperative agreement can be strengthened by enhanced mechanisms to engage with and represent and reflect the perspectives of QHINs, their Participants and Participant Members as the Common Agreement and QTF evolve over time and especially for enhancements that do not conflict with ONC policy imperatives.

- We continue to support the role of the QHIN in the TEFCA process, agree with ONC's proposed high-level criteria to qualify as a QHIN and appreciate that ONC has made changes (e.g., elimination of the Connectivity Broker concept and limits on participating in other agreements) that should enable a wider variety of organizations to qualify as QHINs. To this end, we ask ONC to clarify that it is the collective capabilities of the QHIN and its constituents that are to provide the level of standards-based connectivity to other QHINs required by the MRTCs, whether that QHIN uses a more federated, centralized, or mixed model.

- We agree with ONC that the TEFCA should not dictate the internal requirements nor structures of QHINs or their components.

- We support the revised exchange modalities and associated definitions proposed by ONC. We emphasize that targeted queries are very common in our experience; we appreciate that Draft 2 seems more supportive of the role of targeted queries by QHINs (as well as by Participants and Participant Members) and encourage continuation of that approach as the Common Agreement is finalized.

- The TEF Draft 2 has a revised and narrowed set of Exchange Purposes. We understand the rationale for narrowing Payment and Operations based on comments received but are also very concerned that these revisions could exclude important use cases that would benefit from TEFCA-enabled exchange. At a minimum, we recommend that ONC provide definitions for the revised Exchange Purposes in the

final TEFCA definitions that explicitly state that case management and care coordination are required Exchange Purposes. Fundamentally however, we believe that the full scope of Payment and Health Care Operations, as defined by HIPAA, should be included as Exchange Purposes under the TEFCA, with flexibility provided on what exactly is required for immediate support.

- We agree that QHINs, Participants, and Participant Members should be required to respond to all requests they receive for any of the Exchange Purposes with EHI that they have available (i.e., non-discrimination), to the extent that the organization is authorized by law and its Business Associate Agreements and other partner agreements/contracts (which are in fact legal obligations) to release information for those Exchange Purposes. In addition to HIPAA "minimum necessary" provisions, we suggest that TEFCA participants have some flexibility, guided by the MRTCs and the QTF, to provide the EHI necessary for the applicable use case.

- We ask ONC to be more explicit regarding how fees charged by Participants and Participant Members are handled as part of the Common Agreement, including any limits on such fees or requirements for transparency and disclosure.

- We agree with ONC that, "QHINs, Participants, and Participant Members are in no way limited from voluntarily offering additional exchange modalities and services or from entering into point-to-point or one-off agreements between organizations that are different from the Common Agreement's MRTCs, provided that such agreements do not conflict with the policies of the Common Agreement". We urge ONC to provide greater clarity regarding what it means to "not conflict with the . . . Common Agreement". ONC should be clear that other agreements that do not involve operations under the TEFCA are permitted to reflect different policy conclusions than does the CA, if the organization's participation under the CA is fully compliant with its terms. More generally, we ask ONC to be clear that participating in alternate (i.e., non-TEFCA) trust agreements is permitted for TEFCA signers.

- We strongly agree with ONC that "[e]stablishing baseline privacy and security requirements shared by all QHINs, Participants, and Participant Members is important for building and maintaining confidence and trust that EHI shared pursuant to the Common Agreement is appropriately protected". We do, however, urge ONC to be clear on when non-HIPAA covered entities or business associates must meet all HIPAA privacy and security protections versus specific requirements in the MRTCs.

- We suggest that ONC allow less global Meaningful Choice exercises than proposed.

- Based on what we have learned from our partner organizations, we encourage ONC to assess the viability and level of burden of requiring private sector organizations to conduct security assessments related to NIST 800-171 as well as the applicability of the Controlled Unclassified Information (CUI) requirements to the private sector.

- We appreciate ONC's intent to potentially require a narrower approach to security labeling than might otherwise be the case but believe such a labeling policy is premature and its adoption could greatly slow initial implementation of the TEFCA. We suggest that labeling could be addressed at a later point through ARTC revisions.

- We agree, in general, with each of the proposed high-level principles in the TEF Draft 2 but are uncertain about the extent to which these principles are intended to guide the actions of exchange participants as distinct from the MRTCs, the ARTCs, and the QTF. As part of our detailed comments, we ask ONC to be explicit and clarify its expectation and requirements for application of these principles, clarifying that they have no compliance implications.

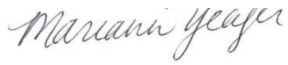
- We strongly agree with ONC that the RCE will combine the MRTCs with the RCE-developed ARTCs into a full data sharing agreement, the Common Agreement. We suggest that the Common Agreement provide for phasing in of modalities or specific requirements (e.g., meaningful choice and messaging). Such staging would allow for a faster and less disruptive roll-out of the TEFCA by the RCE. In the attached appendix, we comment selectively on specific MRTCs. In addition, as stated, we believe that the RCE should have an important role in finalizing the MRTCs.

- We generally agree with the perspectives in the Overview section on the QHIN Technical Framework (QTF). We strongly agree with ONC's proposal that the RCE finalize the QTF based on comments received and urge that consideration of comments and external engagement extend beyond this initial comment period. We generally agree with the standards and profiles proposed for the various use cases and purposes and emphasize that the final QTF will likely require further constraints on some of these profiles. We respond to several of ONC requests for information regarding aspects of the QTF. We also suggest that ONC consider extending the QTF completion date to allow for additional stakeholder feedback.

Conclusions

We thank ONC for providing the opportunity to comment on the second draft of the TEFCA. The Sequoia Project is eager to assist ONC in advancing our national interoperability agenda.

Most respectfully,



Mariann Yeager
CEO, The Sequoia Project

cc: Jon White, MD
Elise Sweeney Anthony, JD
Steven Posnack, MS, MHS

Appendix: Specific Recommendations and Comments

Introduction to the Trusted Exchange Framework and Common Agreement (TEFCA)

Before commenting on the three appendices to this document, we provide overview comments.

- Key elements of the Cures provision that authorizes the TEFCA in SEC. 4003. INTEROPERABILITY, (b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE state:

  > "(iii) EXISTING FRAMEWORKS AND AGREEMENTS.— The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks; and
  > (v) CONSIDERATION OF ONGOING WORK.—In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.''

  Comment: We urge ONC, in reviewing and responding to comments, to be very mindful of the congressional intent that the TEFCA avoid disruption and duplication of "existing exchanges between participants of health information networks". In our view, as drafted, the TEFCA would both disrupt and duplicate existing exchanges and would require extensive changes to existing activities and revisions to the terms of thousands of legal agreements. As ONC considers our comments and those of others, we urge that it look for every opportunity to minimize or eliminate such duplication and disruption, especially in the need to revise legal agreements that have, in many cases, taken years to be developed and ratified.

  ONC notes that "[c]urrently, there are more than 100 regional health information exchanges and multiple national level organizations that support health information exchange. While these organizations have made significant progress in advancing interoperability, connectivity across HINs is still limited due to variations in the participation and data use agreements that govern data exchange."

  Comment: We appreciate the recognition of the current extent of health information exchange and the progress that has been made. We are not, however, convinced that cross-HIN connectivity is primarily still limited by "variations in the participation and data use agreements that govern data exchange". It is important to recognize that variations in agreements often reflect differences in organizational purpose, participants, legal structure, and contracting model, differences that would not or could not necessarily be eliminated by a TEFCA.

  In addition, we note the rapid growth of the Carequality trusted exchange framework, which has been specifically designed to reduce variations in participation and data use agreements. The Carequality community includes regional and national HIEs and other

exchange networks, including CommonWell Health Alliance and the eHealth Exchange. It includes 18 Implementers (including the two largest and most successful vendor-based networks as well as the eHealth Exchange) and 16 others that have signed the Carequality Connected Agreement (CCA) and are in various stages of the onboarding process.

When current Implementers are fully rolled out, we expect Carequality to cover approximately 90% of U.S. providers, based on EHR market share and HIE coverage area. We expect that number to continue to grow as Carequality adds new Implementers. Growth also continues with respect to the remaining group, with service providers emerging with QHIN-like offerings to connect a variety of organizations including smaller and niche EHR vendors. In addition to traditional EHR users, we also are seeing significant and growing participation from long term care, home and hospice care, EMS services, and behavioral health. Consistent with congressional intent, the TEFCA should recognize, preserve, and build on this progress. We do acknowledge that, to date, there has not been as much momentum for supporting non-treatment exchange purposes. We do not believe this gap can be closed either through Carequality's terms or the TEFCA. Rather, we believe that other mechanisms, such as government incentives or the Information Blocking rules, would more likely drive adoption for these purposes.

- ONC notes that "[t]he industry has done significant work to broaden the exchange of data, build trust frameworks, and develop participation agreements that enable providers to exchange data across organizational boundaries. A national exchange agreement must leverage what is working well to encourage and facilitate growth."

  Comment: We agree with this observation and underscore the importance of leveraging what is working, which is substantial, and minimizing disruption, including the time and resources needed to revise exchange agreements and to develop and deploy an alternate technology framework. Fundamentally, the TEFCA should address real, material gaps in current exchange networks, frameworks and agreements. One area where we believe that the TEFCA can add real value is harmonization of agreed upon purposes for exchange.

- In developing a TEFCA, that meets the industry's needs, ONC identifies three high-level goals:

  - Provide a single "on-ramp" to nationwide connectivity;
  - Enable Electronic Health Information (EHI) to securely follow the patient when and where it is needed; and
  - Support nationwide scalability.

  Comment: We support these three goals. We note in particular that the Carequality trust framework is explicitly and successfully designed to provide a single on-ramp and to reduce the extent to which "health systems and providers . . . must join multiple networks that do not connect with one another in order to receive the information they need to care for their patients" for the same exchange purpose.

- ONC will develop Minimum Required Terms and Conditions (MRTCs), described as "mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply." In addition to the MRTCs, the Common Agreement (CA) would include Additional Required Terms and Conditions (ARTCs): that are necessary for an effective data sharing agreement. The RCE will develop the ARTCs and ensure that the ARTCs do not conflict with the MRTCs. ONC will have final approval of the Common Agreement.

  Comment: We support the responsibility of the RCE to develop the ARTCs, subject to ONC approval. At the same time, because the ARTCs must be consistent with and not revise the MRTCs, we believe that the RCE should also have an important role in finalizing the MRTCs in collaboration with ONC. Both the legal language and operational requirements in the MRTCs would benefit from material RCE input. In addition, it will be important for the RCE to have some discretion to be flexible in application of mandatory CA terms to ensure that the TEFCA can be implemented in as non-disruptive and successful a manner as possible. We suggest that the RCE work with prospective QHINs to establish a roadmap to adoption of ARTCs and MRTCs to provide a manageable migration, rather than effectively creating a parallel framework that one must adopt in whole (while also continuing to support the existing framework to maintain existing exchange).

- In contrast to Draft 1 of the TEFCA, ONC proposes that the Qualified Health Information Network (QHIN) Technical Framework (QTF) would be incorporated by reference in the Common Agreement and finalized by the Recognized Coordinating Entity (RCE).

  Comment: We strongly support this approach for the reasons outlined in our comments on Draft 1 and appreciate ONC's responsiveness to comments received.

- The TEFCA is designed to use a "network of networks" structure, which allows for multiple points of entry and is inclusive of many different types of health care stakeholders, examples of which are detailed by ONC.

  Comment: We agree with the network of networks model and ONC's recognition that there could be many types of TEFCA participants. Based on our experience, we note that the simplified three-tier model of QHINs, Participants, and Participant Members (along with Individual Users) does not reflect the full complexity of on the ground realties, although it is useful to illustrate the need for flow-down relationships and provisions (e.g., based on current experience, the Carequality model allows for multiple levels of Participant/Participant Member structures to reflect the variety of organizational constructs, while still enforcing flow down of applicable terms and conditions.)

- ONC proposes to establish a Recognized Coordinating Entity (RCE), an industry-based entity, to implement and monitor compliance with the Common Agreement on behalf of ONC. It sets out several criteria for selection of the RCE.

  Comment: We agree with the role of an experienced private sector RCE, the criteria for the RCE, and the tasks to be completed. We appreciate ONC's clarification, in its

FAQs on "affiliation" of the RCE with an "operating entity" that would otherwise qualify as a prospective QHIN. We specifically agree with and support the FAQ definition (Week of May 10, 2019) of two parties being affiliated "if one has the power to control the other, or if both parties are under the common control or ownership of a common owner." In implementing provisions on affiliation and independence, we ask ONC to recognize that an organization meeting the RCE criteria is likely to have developed a variety of organizational relationships in the stakeholder community given the success that makes it a qualified RCE candidate.

In addition, The Sequoia Project has learned valuable lessons about effective governance including, but not limited to, that governance derives from the consent of the governed and that any governing body must be representative of and responsive to the governed. We have also learned that an enduring trust framework requires a common set of rules known to all participants, consequences for breaking these rules, and a governing body that can enforce these consequences. Our experience also shows that a solid trust agreement foundation can support an evolving set of use cases without having to routinely change the underlying legal framework.

In general, we believe that the proposed TEFCA is designed to achieve the latter three criteria but believe that the final TEFCA and associated RCE cooperative agreement can be strengthened by enhanced mechanisms to engage with and represent and reflect the perspectives of QHINs, their Participants and Participant Members as the Common Agreement and QTF evolve over time and especially for enhancements that do not conflict with an ONC policy imperative.

- The TEF Draft 2 refines the concept of a Qualified Health Information Networks (QHIN), which is "an entity with the technical capabilities to connect Participants on a nationwide scale". A QHIN must meet the definition of a Health Information Network (HIN) and satisfy all conditions of the Common Agreement and accompanying QTF.

  Comment: We continue to support the role of QHINs in the TEFCA. We agree with ONC's proposed high-level criteria to qualify as a QHIN and appreciate that, in response to comments, ONC has made changes that should enable a wider variety of organizations to qualify as QHINs. With respect to the definition of an HIN in the TEF Draft 2, we agree with the broad definition in the context of the TEF, as bounded by the operationally focused QHIN criteria. We note that The Sequoia Project expressed concern to ONC in regulatory comments that the HIN definition in the recent ONC proposed rule implementing 21st Century Cures (Cures) information blocking provisions is too broad for information blocking enforcement purposes. As a result, we suggest that ONC allow, as needed, different definitions of a HIN for information blocking enforcement and for the TEFCA.

  With respect to the QHIN application process, we appreciate the rationale for creating QHIN Cohorts but suggest that ONC be open to elimination of this step once the initial phase of QHIN selection has been completed as it introduces additional administrative complexity and may inappropriately delay advancement of otherwise qualified HINs to QHIN status.

We also agree with ONC's revision that enables QHINs to contract with one or more external entities that provide Connectivity Services and its shift from the Draft 1 provision that QHINs must offer prescriptive Connectivity Broker services. It is our understanding, and we agree, that a QHIN need not have or contract with a Record Locator Service (RLS) if it uses a federated query or other model to identify the applicable data required to respond to a query. More generally, we ask that ONC clarify that a centralized brokered approach, where all data would effectively flow through a centralized QHIN server, is not a prerequisite; rather various degrees/variations of federated and/or centralized models are acceptable. In that context, again, there should also not be a requirement to contract with an RLS even if a centralized, brokered model is used.

- ONC notes that the TEFCA is intended to serve many different stakeholders across the country who have unique needs and constituencies and that its components are not intended to "dictate the internal requirements or business structures of QHINs, but rather provide QHINs flexibility to provide different services and support different stakeholders". It defines Participants, Participant Members, and Individual Users as being under the umbrella structure established by a QHIN.

  Comment: We agree with ONC that the TEFCA should not dictate the internal requirements or structures of QHINs or their components. We also agree that there is a range of potential Participants and Participant Members. As indicated above, we caution that this three-tier model overly simplifies the reality in the field.

- The Common Agreement requires that QHINs support a minimum set of exchange modalities and Exchange Purposes for sending and receiving EHI.

  Comment: We support this requirement.

- ONC proposes a revised set of exchange modalities: QHIN Targeted Query, QHIN Broadcast Query, and QHIN Message Delivery.

  Comment: We support the revised set of initial exchange modalities and associated definitions proposed by ONC, including removal of population-level queries and addition of a message-based modality, reflecting ONC's responsiveness to comments received. We emphasize that targeted queries (and the use cases that support targeted queries) are very common in our experience; we appreciate that Draft 2 seems more supportive of the role of targeted queries by QHINs (as well as by Participants and Participant Members). We agree with ONC that, "[w]hile QHINs must have the capability to perform Broadcast Query, Targeted Query, and Message Delivery, they may use different exchange modalities for different situations." For message delivery, we believe that the evolution of the QTF should accommodate changes needed over time in QHIN to QHIN messaging standards and technologies.

- The TEF Draft 2 has a revised and narrowed set of Exchange Purposes: Treatment, Payment (Utilization Review), Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development), Public Health, Individual

Access Service (includes HIPAA right of access and its equivalent), and Benefits Determination.

Comment: We understand the rationale for narrowing the supported Payment and Health Care Operations purposes based on comments received but are also very concerned that these revisions could exclude important use cases that would benefit from TEFCA-enabled exchange. We note that under the current model, the ARTCs could not be used as a vehicle to expand the exchange purposes in these categories and suggest that ONC consider enabling the RCE and ARTC process to do so.

For Health Care Operations, we emphasize that the HIPAA definition of "quality assessment and improvement activities" has been summarized by HHS to include "case management and care coordination," although the formal definition at 45 CFR §164.501 does not include these activities under the same sub-definition. At minimum, we recommend that ONC provide definitions for the revised Exchange Purposes in the final TEFCA definitions that explicitly state that case management and care coordination are required Exchange Purposes.

Fundamentally however, we believe that the full scope of Payment and Health Care Operations, as defined by HIPAA, should be Exchange Purposes under the TEFCA, with flexibility on what exactly is required for immediate support. For example, the MRTCs could permit the full extent of Payment and Health Care Operations exchange but not require all Participants and Participant Members to fully support these purposes. It is important to strike a balance between what is required and what is permitted, and the ARTCs and the QTF can assist in that goal to some degree.

- ONC states that QHINs, Participants, and Participant Members must respond to all requests for EHI they receive for any Exchange Purposes with EHI they have available.

  Comment: We agree with this requirement, including the recognition that the obligation to share only extends to EHI that is available. We do ask ONC to be more explicit regarding how fees charged by Participants and Participant Members are to be handled as part of the Common Agreement, including any limits on such fees or requirements for transparency and disclosure. We assume that fees charged by a Participant or Participant Member would only affect a requesting QHIN insofar as the QHIN associated with a responding Participant or Participant Member chose to charge a fee to the requesting QHIN consistent with the MRTCs and the ARTCs. ONC might also wish to address how information blocking provisions relating to fees would affect the operation of the TEFCA.

- ONC indicates that it intends to "phase in new exchange modalities and Exchange Purposes in the Common Agreement to support additional use cases". ONC also states that, as it phases in new requirements, "QHINs, Participants, and Participant Members are in no way limited from voluntarily offering additional exchange modalities and services or from entering into point-to-point or one-off agreements between organizations that are different from the Common Agreement's MRTCs, provided that such agreements do not conflict with the policies of the Common Agreement". It emphasizes that the "TEF and the Common Agreement do not limit the ability of HINs

to innovate and build additional services that would provide value to their users and support their long-term sustainability".

Comment: We agree with the intention for a phased approach. At the same time, because additions to Exchange Purposes and Modalities will require updates to legal agreements, ONC should establish as broad an initial baseline as feasible to minimize the need for "one-off" agreements. In addition, the RCE/ARTC process should be able to be used to implement expansions, subject to ONC's approval.

Finally, we agree with ONC's statement regarding the ability of TEFCA participants to provide additional services outside of the TEFCA. This revised language is a material improvement over the Draft 1 provisions on the relationship of other agreements to the Common Agreement. At the same time, we urge ONC to provide greater clarity on what it means to "not conflict with the . . . Common Agreement". ONC should be clear in the final TEFCA that other agreements that do not involve operations under the TEFCA are permitted to reflect different policy conclusions than does the CA, if the organization's participation under the CA (i.e., when the CA is the relevant agreement) is fully CA-compliant. More generally, we ask ONC to be clear that participating in alternate (i.e., non-TEFCA) trust agreements is permitted for CA signers; such flexibility will be very important during the transition to the TEFCA.

- ONC states that "[e]stablishing baseline privacy and security requirements shared by all QHINs, Participants, and Participant Members is important for building and maintaining confidence and trust that EHI shared pursuant to the Common Agreement is appropriately protected".

  Comment: We strongly agree. We do, however, urge ONC to be very clear on when non-HIPAA covered entities or business associates are subject to all HIPAA privacy and security protections or just specific requirements called out in the MRTCs.

- The MRTCs require that QHINs, Participants, and Participant Members enable individuals to exercise Meaningful Choice to request that their EHI not be used or disclosed via the Common Agreement, except as required by law.

  Comment: The MRTCs appear to define Meaningful Choice as an all or nothing action covering all exchange under the TEFCA. We suggest that ONC consider allowing less global expressions of Meaningful Choice that would not require detailed data segmentation, perhaps allowing choice to be exercised for data held at a specific QHIN, Member or Member Participant. We also emphasize that the very act of exercising Meaningful Choice as broadly as envisioned means that information about individuals is more widely distributed than they might wish. We also note that there is no widely agreed upon and adopted standard for communicating this information in the manner expected.

- ONC is considering inclusion of a new security labeling requirement. Recognizing that Data Segmentation for Privacy (DS4P) and the associated HL7® implementation guide

have not received wide adoption, ONC indicates that it is considering a somewhat focused security labeling policy.

Comment: We appreciate ONC's intent to potentially require a narrower approach to security labeling than might otherwise be the case but believe that such a policy remains premature and its adoption could greatly slow initial implementation of the TEFCA. We suggest that security labeling could be addressed at a later point through ARTC revisions.

Trusted Exchange Framework (TEF)

- According to ONC, the Trusted Exchange Framework (TEF) Draft 2 describes "a common set of principles that facilitate trust between HINs". These principles would serve as "rules of the road" and ONC states further that "[b]road adherence to these principles will minimize variation in technical and legal policies that restrict the secure flow electronic health information (EHI)".

  Comment: In general, these principles are reasonable. We comment selectively below based on our experience. We are uncertain however, about the extent to which these principles are intended to guide the actions of exchange participants as distinct from the MRTCs, the ARTCs, and the QTF. We note, for example, that Principle 6 – Population Level Data is no longer associated with an initial MRTC exchange purpose. We suggest that ONC be explicit and clarify its expectation and requirements for application of these principles, being clear that they have no compliance-related implications. It would also be useful for ONC to map the MRTCs, ARTCs, and QTF to these principles.

  Comment: Much of the language in the principles refers to "HINs" as opposed to QHINs, Participants, or Participant Members. We urge ONC to clarify to which entities the principles are intended to apply.

  Comment: Principle 5 – "Access: Ensure that Individuals and their authorized caregivers have easy access to their EHI" seems to assume that HINs must act like HIPAA Covered Entities and maintain APIs and policies that directly support the HIPAA right of access, including the right to direct EHI to a third party. This principle seems to be an overly broad expansion of current understandings of HIN obligations, which would be implemented through Business Associate Agreements in many cases, and one that is also not directly supported by the MRTCs or the QTF. We urge ONC to consider carefully comments that it receives from relevant stakeholders and to clarify this principle.

Minimum Required Terms and Conditions (MRTCs)

- According to ONC, the RCE will combine these MRTCs as well as Additional Required Terms and Conditions (ARTCs), developed by the RCE and approved by ONC, into a full data sharing agreement, the Common Agreement.

  Comment: We strongly agree with this approach. We comment selectively on specific MRTCs. In addition, as discussed previously, we believe that the RCE should have an important role in finalizing the MRTCs. Both the legal language and operational requirements in the MRTCs would benefit from material RCE input.

1. Definitions

- Connectivity Services

  Comment: We agree with the shift between Draft 1 and Draft 2 from "Connectivity Broker" to "Connectivity Services". We agree with what we believe to be ONC's intention that a QHIN need not have or use a Record Locator Service (RLS) or an enterprise master patient index (EMPI) if these are not needed to implement their Common Agreement obligations. It is important that ONC not dictate a specific architecture or technology in the MRTCs.

- Exchange Purposes

  Comment: We are unclear why ONC defines Exchange Purposes in the first paragraph very narrowly as "Use or Disclosure" and then in the second paragraph of the definition "for the avoidance of doubt" has as broader definition more in accord with a common sense understanding of exchange purposes. In addition, as discussed above, we believe that, at minimum, ONC should provide definitions for the revised Exchange Purposes in the final TEFCA definitions that explicitly state that case management and care coordination are required Exchange Purposes. We do, however, fundamentally believe that full Payment and Health Care Operations, as defined by HIPAA, should be TEFCA Exchange Purposes, with flexibility provided on what exactly is required for immediate support.

- Health Information Network (HIN)

  Comment: As indicated above, we agree with ONC's proposed broad definition of "HIN" in the TEFCA Draft 2, as bounded by the operationally focused QHIN criteria. We do believe, however, that the HIN definition used in the recent ONC proposed rule implementing 21st Century Cures (Cures) information blocking provisions is too broad for information blocking enforcement purposes and suggest that ONC allow, as needed, different definitions of a HIN for information blocking enforcement and for the TEFCA.

- Individual Access Services

  Comment: We have concerns that ONC unduly bounds this concept with its linkage to specific regulatory provisions and seems to envision participation in the ecosystem by consumers only occurring when the individual "shows up" (literally or virtually) at the medical records department and asks for their record. We suggest that this model be broadened to enable query-based access to the TEFCA network by individuals, via APIs or other means supported by the TEFCA, in a manner that is generally equivalent to the query-based access by TEFCA entities.

- Meaningful Choice

  Comment: The MRTC appear to define Meaningful Choice as an all or nothing action covering all exchange under the TEFCA. We suggest that ONC consider allowing less global Meaningful Choice exercises that would not require detailed data segmentation perhaps allowing choice to be exercise for data held at a particular QHIN, Member or Member Participant. We also suggest that ONC consider stakeholder comments on its proposal that choice can only operate on a "prospective" (i.e., going forward) basis.

- QHIN Targeted Query

  Comment: The MRTCs define a QHIN Targeted Query as "a QHIN's electronic request for an Individual's EHI . . . from specific QHINs . . .". We ask ONC to clarify our understanding that a QHIN can itself initiate what is effectively a targeted query within its Participants to satisfy either a QHIN Broadcast or QHIN Targeted Query, and whether Participants and participant Members can do the same.

2. Initial Application, Onboarding, Designation and Operation of QHINs

2.1 Initial Application, Onboarding, and Designation

Comment: Overall, these MRTCs are reasonable. We have a few comments below:

- *2.1.3—Requirements for Approval of a QHIN Application: We suggest that ONC provide additional clarification regarding how it defines the term "already" for the requirement that a prospective QHIN "already operates a network . . .". We also suggest that "already" means at the time of the application for QHIN status and that ONC clarify that the RCE has the authority to interpret and implement this and similar provisions.*

  Also, in Section 2.1.3(iii), the MRTCs state, in the context of pre-requisites for having an application be approved and thus advance to the Provisional QHIN status: "the HIN has provided reasonable evidence that exchange of EHI using its network is occurring in accordance with Applicable Law and the requirements of Section 6 below". It is highly unlikely that any HIN's existing exchange activities are completely in accordance with the MRTC Section 6. Although most prospective QHINs will be generally compliant with such provisions, there are many specifics in Section 6 (e.g., documentation expected, as

well as requirements related to Controlled Unclassified Information) that may be new for many HINs. It is unreasonable to expect prospective QHINs to proactively modify agreements and operational processes to completely align with these requirements before they have certainty that they will even be accepted as a Provisional QHIN. Other aspects of the QHIN application process acknowledge that applicants will likely have work to do once they sign, to fully align with the CA and QTF requirements. It is unclear why this approach would not apply to Section 6. We suggest that the applicable language in 2.1.3(iii) be modified to: "the HIN has provided reasonable evidence that exchange of EHI using its network is occurring in accordance with Applicable Law".

- *2.1.6—Requirements for QHIN Designation: The MRTC states that a "Provisional QHIN shall automatically become a QHIN upon receipt of written QHIN Designation from the RCE". We note that there will, of necessity, be a period between designation and being fully live; during this period the QHIN would have formal obligations that it may not be able to meet as it moves to full operational status. We urge ONC to clarify that the RCE has authority to exercise discretion and manage this transition.*

2.2 QHIN Operations

Comment: Overall, these MRTCs are reasonable. We have a few comments below:

- *2.2.1(ii)(a)— The MRTC states that "[w]hen a QHIN receives a QHIN Query from another QHIN, the QHIN shall request EHI from appropriate Participants . . .". Similar to our comment above regarding the definition of a Targeted QHIN Query, we ask ONC to confirm our understanding that a QHIN (and subsequently its Participants) has discretion to determine who "appropriate Participants" for the query are. We ask ONC to confirm our understanding that a QHIN receiving a query will also not likely know whether the query is targeted or broadcast.*

- *2.2.3—Individual Exercise of Meaningful Choice: The MRTCs appear to define Meaningful Choice as an all or nothing action covering all exchange under the TEFCA. We suggest that ONC consider allowing less global exercises of Meaningful Choice that would not require detailed data segmentation, perhaps allowing choice to be exercised for data held at a specific QHIN, Member or Member Participant. In addition, the very act of exercising Meaningful Choice as broadly as envisioned means that information about individuals is more widely distributed than they might wish. We also note that there is no widely agreed upon and adopted standard for communicating this information in the manner expected.*

  We also suggest that ONC consider stakeholder comments on its proposal that choice can only operate on a "prospective" (i.e., going forward) basis and also ask ONC to clarify that information that was released prior to the exercise of Meaningful Choice (e.g., a summary of a patient's medical record as captured in a C-CDA) cannot be re-released by the same QHIN, Participant, or Participant Member after the exercise (as opposed to the ability for continued use of such data when it has been incorporated in a locally maintained legal medical record).

- *2.2.4—Processing of Individual Access Services Request: We have concerns that ONC unduly bounds this concept with its link to specific regulatory provisions (in the definition) and seems to envision participation in the ecosystem by consumers only occurring when the individual "shows up" (literally or virtually) at the medical records department and asks for their record. We suggest that ONC expand this concept to envision and include a more regular, authorized query process.*

  In (ii), ONC states that "[w]hen the QHIN is acting as a Business Associate and the request for Individual Access Services is received by a Covered Entity that directs the QHIN to satisfy the request, then the QHIN may respond to a request for Individual Access Services if permitted or required by the terms of the applicable Business Associate Agreement". We do not understand why a QHIN's obligation is expressed as "may" if it is directed by a Covered Entity to which it is a Business Associate.

- *2.2.6—Mandatory Updating of Participant-QHIN Agreements and 2.2.7—Failure to Incorporate Mandatory Minimum Obligations in Participant-QHIN Agreement: We suggest that ONC shorten the period from 18 months to 6 months in 2.2.6 for mandatory updating of agreements and then, critically, relax 2.2.7, for a period of time, from failure to implement being a material breach to the QHIN assuming responsibility/liability for any fallout from its community not having been legally bound to updated terms.*

  Fundamentally, we believe that agreements should be updated quickly but that compliance deadlines should reflect the nature of specific agreement changes and associated implementation implications, especially those that require major technical or process changes. Similarly, if there is a major change in the CA that expand Exchange Purposes or requires a new technology approach, the period to update the agreements could still be shorter than 18 months but with a longer period before failure to implement is a material breach.

4. Transparency

Comment: Overall, these MRTCs are reasonable. We have a few comments below.

4.1 Agreements and Fee Schedules

Comment: These provisions appear burdensome and ONC is not clear what the RCE would do with Agreements and Fee Schedules, including information of fee waivers. ONC should be clear about any RCE obligations to act on the provided information and that the purpose of this disclosure is to enable the RCE to implement MRTC provisions, such as section 5.2 as well as ARTCs that apply to fees.

4.2 Disclosures for Specific Purposes

Comment: It is unclear why or when a QHIN would have information (other than obtained as part of a query) relevant to "reporting of EHR-related adverse events,

hazards, and other unsafe conditions to government agencies, accrediting bodies, patient safety organizations . . . [or] (ii) participating in cyber threat sharing activities" and who are the authorized requesters referenced in "upon request". Would these be the entities to whom this information is being disclosed? If the QHIN is a business associate, could its Business Associate Agreements limit disclosure of such information? To that end, this provision should only apply to information that the QHIN has by virtue of its QHIN status.

5. Cooperation and Non-Discrimination

Comment: Overall, these MRTCs are reasonable. We have a few comments below.

5.1 Non-Discrimination

Comment: We agree with the principles underlying "5.1.2—No Discriminatory Limits on Exchange of EHI," but believe that no QHIN should be able to impose any testing requirements on other QHINs (or their Participants, or Participant Members) for exchange governed by the Common Agreement, except what is required by the RCE for designation as a QHIN. This proposed revision is very important. A major reason for the success of Carequality is that once an organization onboards, it is connected to "everyone". The need for individual testing and other such processes with every other QHIN will hamper adoption and growth. In addition, we suggest that "5.1.3—Updates to Connectivity Services" be removed from the MRTCs; such Service Level Agreements will likely be needed in the ARTCs and, as written, this provision will be difficult to enforce.

5.2 Fees

Comment: For "5.2.1—Reasonable and Non-Discriminatory Fees," we suggest that ONC, not the RCE, manage evaluation of fees against Reasonable and Nondiscriminatory (RAND) criteria if this requirement remains in the MRTCs or ARTCs. If ONC does not assume this responsibility, it will be very important for ONC to provide technical assistance to the RCE on implementation of RAND fees. In addition, we suggest that ONC clarify the implications of its statement that "[n]othing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN". If a QHIN chooses not to pay a fee charged by another QHIN, does that mean that the first QHIN is not obligated to exchange with the QHIN that charges fees?

6. Privacy, Security, and Patient Safety

Comment: Overall, these MRTCs are reasonable. We have a few comments below.

6.2 Minimum EHI Security Requirements

Comment: For "6.2.1—Application of NIST Standards and ONC/OCR Security Risk Assessment Tool," for "(ii), Protecting the Confidentiality of Controlled Unclassified Information (CUI) in Non Federal Systems and Organizations". Based on what we have learned from our partner organizations, we encourage ONC to assess the viability and level of burden of requiring private sector organizations to conduct security assessments related to NIST 800-171 as well as the applicability of the CUI requirements to the private sector. Specifically, we have heard many concerns about the ambiguity and necessity of CUI and associated requirements for private sector organizations and variances from HIPAA requirements.

For "6.2.2—Data Integrity," we question the feasibility or value of the proposal that "[e]ach QHIN shall report known instances of inaccurate or incomplete EHI to the Participant who is the originator of the EHI, and request that the Participant remediate such data integrity issues in a timely manner to the extent reasonably possible". This provision does not distinguish between a QHIN's own Participants and those of another QHIN. More fundamentally, when would a QHIN know if EHI is inaccurate and how is "incomplete" defined? It is unclear when a QHIN would have the data access or information to identify such issues.

For "6.2.3 Authorization," we ask ONC to confirm if this provision only applies to QHIN-to-QHIN transactions, which should be addressed by the QTFs, or also to Participants querying through the QHIN. More clarity would be helpful.

For "6.2.4 Identity Proofing," and "6.2.5 User Authentication," we are concerned that rigid and universal required operational application of these requirements for QHINs, Participants and Participant Members could deter organizations from participating in the TEFCA and we question the need for and value of application of these requirements as proposed.

For 6.2.6, 6.2.7, and 6.2.8, it is unclear why the MRTCs address in detail compliance with QTF provisions, compliance that would need to be validated by the RCE. It would be simpler to focus on QHIN compliance with the QTF.

For "6.2.9—Certificate Authority Backup and Recovery," we question whether many QHINs would also be certificate authorities and why, if they are in a function unrelated to their QHIN role, such a provision is needed.

7. Participant Minimum Obligations

Comment: See prior comments on QHIN obligations. We have selected comments below. In general, as discussed above, we believe that the three-tier hierarchical architecture envisioned by ONC may not fully reflect the complexity of current reality. To accommodate more complex architectures, it may make sense to combine Sections 7 and 8.

7.1 Exchange Purposes and EHI Reciprocity

Comment: On (ii), we ask ONC to confirm our understanding that Participants are not expected to know whether the QHIN received a Broadcast or Targeted Query and have discretion, consistent with the phrase "shall request EHI from appropriate Participant Members", to determine which Participant Members should be queried based on the information contained in the query. We also ask ONC to clarify that, with respect to the EHI to be disclosed in response to a query, the Participant has an obligation to respond consistent with what is permissible under law and cannot simply refuse to disclose as a result of a claim that it cannot determine consistency with an exchange purpose or with minimum necessary requirements.

Our concern is that the current wording of the terms around query responses leaves the door open to an organization never honoring queries for non-treatment purposes. They could claim an inability to release information in a way that is compliant with Minimum Necessary as described in 7.19 (or any applicable law requirement), and then never correct this lack of ability. Similar to our comments on Exchange Purposes in general, we suggest that ONC work with the RCE to establish reasonable requirements in the ARTCs around mandatory participation (or lack thereof) in the various Exchange Purposes, such that it is clear that a lack of functional capability cannot be used as an excuse for not being able to participate in anything meant to be mandatory.

8. Participant Member Minimum Obligations

Comment: See our prior comments on QHIN obligations. We have selected comments below.

8.1 Exchange Purposes and EHI Reciprocity

Comment: On (ii), we ask ONC to clarify that, with respect to the EHI to be disclosed in response to a query, the Participant has an obligation to respond consistent with what is permissible under law and cannot refuse to disclose as a result of a claim that it cannot determine consistency with an exchange purpose or with minimum necessary requirements.

9. Individual Rights and Obligations

Comment: Overall, these MRTCs are reasonable.

Qualified Health Information Network (QHIN) Technical Framework (QTF)

Overview

Comment: We applaud ONC's public reinforcement of the RCE's role in finalizing the QTF. We view the QTF Draft 1 as a starting point that will generate useful public comment, which will be

invaluable to ONC and the RCE in developing the initial version of the QTF for operational deployment. We also support ONC's vision of the QTF being updated over time with new capabilities and to address lessons learned. This plan mirrors the approach that Carequality has taken with its Framework documents.

We note that ONC's timeline in this document and the RCE Notice of Funding Opportunity offers limited opportunity for public vetting of the proposed QTF. We understand the need to provide the implementation community with a final QTF as soon as possible, so that any necessary development can begin. There is, however, a need to balance speed and sufficiency and we have some concerns with the sufficiency of the specifications proposed for QHIN Message Delivery and Meaningful Choice communications under the proposed timeline. Effective incentives and motivation, paired with good faith and collaborative intent on the part of participants, can allow exchange to thrive under legal terms that lack clarity. Technical specifications that lack clarity, however, can lead to a fundamental breakdown in exchange activities even in the presence of good faith and collaboration. We suggest therefore that ONC consider extending the QTF completion date to allow for additional stakeholder feedback.

We generally agree with the perspectives in the Overview section and especially appreciate the following:

- "While the Recognized Coordinating Entity (RCE) (to be selected by ONC) will establish the final operational and technical means by which QHINs exchange Electronic Health Information (EHI), the QTF Draft 1 provides an initial set of QHIN technical responsibilities for public comment."

- "The QTF also describes high-level functional requirements QHINs must support within their health information networks. However, the QTF Draft 1 intentionally does not specify standards QHINs must use for these internal-QHIN implementation decisions."

- "The technical and functional requirements described in the QTF Draft 1 reflect many of the technologies and standards used for network-based health information exchange today. For example, organizations supporting health information exchange nationally (e.g., CommonWell Health Alliance, eHealth Exchange, Carequality) generally use Integrating the Healthcare Enterprise (IHE) profiles such as Cross-Community Patient Discovery (XCPD) and Cross-Community Access (XCA) to enable clinical document exchange between disparate communities."

- "Although the healthcare industry has started to explore new exchange modalities, such as Representational State Transfer (RESTful) application program interfaces (APIs) and standards like Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®), the QTF Draft 1 seeks to facilitate the immediate availability of QHIN services."

1. Definitions

Comment: We support ONC's use of the "First Degree Entity" construct and suggest the MRTCs be carefully reviewed to determine if this term could replace the distinction between

Participants and Participant Members. As noted in our earlier comments, the three-tiered hierarchy is likely insufficient to address the full complexity of real-world relationships and deployments and may not be necessary to achieve TEFCA goals.

2. Example QHIN Exchange Scenarios

Comment: We agree with ONC's proposal that the RCE finalize the QTF based on comments received. As such, we provide focused suggestion and comments.

We generally agree with the specified standards and profiles for the various use cases and purposes. These are generally consistent, for example, with those used today by Carequality for queries. We note that Carequality and many other stakeholders use the Nationwide Health Information Network (NHIN) Authorization Framework for Security Assertion Markup Language (SAML) Tokens and suggest that this profile be considered as part of the RCE review of these standards and profiles. We also emphasize that the final QTF will likely require further constraints on some of these profiles, such as XCPD and XCA. Both Carequality and eHealth Exchange needed to constrain these profiles to achieve consistent, scalable implementations. More generally, we urge the RCE to be positioned and enabled to build on what is in production now rather than being required to effectively build a parallel technology stack.

We support ONC's general vision for the QHIN Query workflow. We do note that applying the terminology of "record location" to the XCA Query transaction may create a possibility for confusion because of the range of approaches that can be used to locate records.

We note that the model of routing all communications through the QHIN resolves some challenges, while raising others, particularly in the QHIN Query exchange modes. Allowing First Degree Entities and their constituents to maintain a single connection to their QHIN, rather than to many potential partner systems, simplifies maintenance of connectivity. Document query and/or retrieve operations, however, will likely see some challenges when handled as a single transaction between QHINs, due to the high variability in response times inherent in on-demand document generation, which is widely deployed. There is a risk of the entire transaction being completed at the speed of the slowest underlying responder within a QHIN's network, and timeouts may be frequent. We encourage ONC to pay careful heed to suggestions for resolving these challenges that may come in public comments.

We agree with ONC's naming of widely deployed, existing standards for the QHIN Query function, and with ONC's timing-based rationale for doing so. We encourage ONC, however, to consider publicly stating that its intent is to expand the QHIN Query exchange modality to support FHIR-based exchange in the future.

We suggest that ONC more clearly articulate key use cases for the QHIN Message Delivery exchange modality. It is not entirely clear what the relationship of exchange modality is to existing activities using Direct and IHE Cross-Enterprise Document Reliable Interchange (XDR) standards. Given these questions and the lack of wide adoption for ONC's proposed standard, we encourage ONC to consider a phased approach in which the TEFCA can be brought to

market quickly for QHIN Query while ONC and the RCE work with stakeholders to clearly articulate and specify the QHIN Message Delivery modality.

3. Functions and Technology to Support Exchange

Comment: We generally agree with ONC's proposal for functions and technology to support exchange. We provide specific comments below.

Certificate Policy

- *We support ONC's expectation of collaborative work with the RCE to fully articulate details of certificate and other technical trust considerations.*

Secure Channel

- *Request for Comment #1: We support the proposed requirement for TLS v1.2 or above. This approach is commonly used in many existing deployments and, given the proposed QHIN Query standards, should allow for the least disruption for technical deployments.*

User Authentication

- *Requests for Comment #2: We encourage ONC and the RCE to carefully review comments received.*

Authorization & Exchange Purpose

- *Requests for Comment #3: We encourage ONC and the RCE to carefully review comments received.*

Query

- *Requests for Comment #4: We encourage ONC and the RCE to carefully review comments received.*

- *Request for Comment #5: Some key query parameters will likely need to be addressed, including the Service Start/Stop time parameters.*

- *Request for Comment #6: We suggest that more granular queries be addressed by a future expansion into FHIR-based exchange under the TEFCA framework. It is not realistic to expect that, in the foreseeable future, documents can be queried via reference to details regarding their clinical content. Relevant indices and internal cross-references to make this practical are not generally maintained today, even if a standard were to be proposed for supporting the inclusion of such information in query transactions.*

Patient Identity Resolution

- *Request for Comment #7: We suggest that the QTF require additional parameters beyond those currently required by XCPD. We suggest that ONC and the RCE review and leverage the recommendations in The Sequoia Project's "A Framework for Cross-Organizational Patient Identity Management"— https://sequoiaproject.org/resources/patient-matching/.*

- *Request for Comment #8: We do not believe that the QTF should be prescriptive about QHIN internal technical architectures, including patient matching approaches. Patient matching is an area with much room for innovation and improvement, and it would be unfortunate to be locked into a single approach as the industry evolves new techniques.*

- *Request for Comment #9: The details of requiring specific performance benchmarks for patient matching can be very challenging. This challenge is likely to be especially evident in the TEFCA ecosystem given the expectation of QHIN Broadcast Queries, for which a failure to find a match is often an appropriate outcome. We suggest that ONC work with stakeholders to evaluate real-world patient matching outcomes among QHINs, Participants, and Participant Members to inform future QTF versions but take no specific action on this area in the initial QTF version for production use.*

Record Location

- *Request for Comment #10: We support ONC's allowance of flexibility in QHIN internal models. We note that large-scale QHINs with many Participants, who in turn may have many Participant Members, would likely experience response time challenges if they do not have a centralized (i.e., QHIN-level) Record Locator Service. Nonetheless, we believe that it is important to allow and support other models, so long as a QHIN is able to comply with any enforced SLAs with respect to response time.*

Directory Services

- *Request for Comment #11: We encourage ONC to work with the RCE to develop an operational directory approach. Flexibility for internal QHIN and sub-QHIN directory services is desirable but we believe that the RCE will need to operate or designate an operational directory to facilitate QHIN-to-QHIN communication. Support for this directory will be required for QHINs in practice, but it may be possible to address this requirement in a separate operational policy rather than including it in the QTF.*

Individual Privacy Preferences

- *Request for Comment #12: We agree with ONC's approach to not have the QTF Draft 1 specify a particular technology or standard for QHINs to use to manage Individual privacy preferences. We are not aware of a widely deployed standard that would support the communication of patient opt-out information to support the Meaningful Choice concept effectively across QHINs or more broadly across the TEFCA ecosystem. Even if*

such a standard existed, there is a fundamental patient matching challenge in cross-QHIN opt-out implementation. There are a variety of points at which the opt-out process could break down, both in the short-term and in the future as patient demographics diverge from those associated with the original opt-out. As suggested in our MRTC comments on this issue, we have serious concerns about unmet patient expectations in this environment. We encourage ONC to consider opt-out events to be contained initially within a QHIN, and to address potential enhancements to this approach in collaboration with stakeholders, based on real-world experience within the TEFCA ecosystem.

- *Request for Comment #13: Similarly, we encourage ONC to consider consent collection to be largely internal to a QHIN initially. We note that the SAML token may offer opportunities to provide some consent information within individual queries and suggest that such an approach be explored either for the initial or subsequent production QTF versions. Consent under Applicable Law, including state laws (which can vary greatly between states), may not be readily transferrable or generally relevant to other QHINs and is likely best addressed in the context of specific requests for health information.*

Auditing

- *Request for Comment #14: We encourage ONC and the RCE to carefully review comments received.*

Error Handling

- *Request for Comment #15: In principle, we do believe that the QTF should specify a consistent set of error messages for interactions between QHINs. At the same time, given tight initial time constraints, it might make sense to not aim for a full specification for error handling in the first production version of the QTF.*