EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

33 West Monroe Street, Suite 1700
Chicago, IL 60603

@EHRAssociation | ehra.org

October 21, 2021

Mariann Yeager
CEO
The Sequoia Project
8300 Boone Blvd., Suite 500
Vienna, Virginia 22182

Dear Mariann,

Developing or supporting a national trusted exchange framework is a key objective of the 21st Century Cures Act, and has effectively been a driving force for The Sequoia Project, Carequality, eHealth Exchange and CommonWell. The proposed Trusted Exchange Framework (TEF) Common Agreement (CA) elements indicate that the agreement will build upon the experiences of these national networks, in which many of our members participate and support.

Electronic Health Record Association (EHRA) member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objective is to collaborate to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

On behalf of the nearly 30 member companies of the EHRA, we appreciate the opportunity to share our feedback on the elements of the TEF Common Agreement being considered. The comments and suggestions provided below for each of the elements build on our feedback provided in prior versions of both the TEF CA and QTF.

Sincerely,

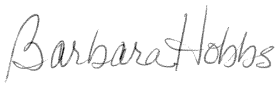
Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee

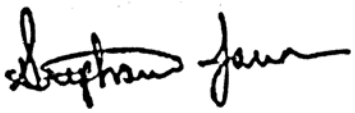
Pamela Chapman
Experity Health

William J. Hayes, M.D., M.B.A.
CPSI



Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health

Alya Sulaiman, JD
Epic

About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS.

For more information, visit www.ehra.org.

Definitions

We note that when referencing "QHIN" it is not always clear whether the reference is solely to the organization that is providing the QHIN services, or is inclusive of all its Participants and Subparticipants. We suggest emphasizing that QHIN solely references the organization that is providing the QHIN services, unless it is specifically expanded to cover all participants. For example, when it is stated in 13. Fees that QHINs cannot charge each other, is that solely the organizations providing the QHIN services, or inclusive of any of its Participants and Subparticipants?

We note that the definition of "available" is unclear in "5. TEFCA Information and Required Information - ...A QHIN, Participant, or Subparticipant that receives a request would be obligated to provide all Required Information that is *available* for the Exchange Purpose asserted…" We agree this is an appropriate concept to establish expectations regarding what data should be shared. We suggest, however, that this be further defined using the context of information blocking rules to align on data sharing requirements. It should address when "available" creates an obligation to share data considering the capabilities of the technology a Participant or Subparticipant has available, and the forms of the data that are available considering the required standards and specifications that are part of trusted exchange. It should also address whether EHI (a subset of the ePHI that makes up Required Information) maintained in a Participant's system that is "disconnected" from trusted exchange that otherwise would fit within a required purpose of exchange use case should or should not be considered "available" when it would otherwise be considered information blocking.

Exchange Purposes

We appreciate the intent to support a broad set of exchange purposes. Current deployments indicate that the "Treatment" purpose is being widely supported and "Individual Access Services" is advancing, while there is minimal, if any, adoption of the other exchange purposes. This is due to a combination of factors: readiness of stakeholders on both sides of the interoperability use cases that support the relevant standards and technologies, due to conflicting priorities or lack of funding, and absence of sufficient guidance as to what data sets are appropriate to access and exchange, particularly using a query model. The EHRA recommends a phased approach to supporting the exchange purposes, starting with "Treatment" and "Individual Access Services," and expanding as implementation guides for subsequent exchange purposes are incorporated into the QTF. Such implementation guides would also provide clear understanding of data sets/documents that can be shared to align with minimally necessary and fit for purpose considerations rather than being required to send all data on a patient in all circumstances. We suggest that such guidance, including summary grids on what data is expected to be shared for each use case, is best provided by expanding the QTF and SOPs as appropriate. Once available, QHINs, Participants, and Subparticipants can proceed with the necessary development and wide deployment. We note that based on ONC's certification program, initializing wide deployment typically takes 18-24 months from the availability of specifications, depending on other regulatory requirements.

"...shared through QHIN-to-QHIN exchange..." and "Requests: TEFCA requests would be transmitted via a QHIN's Connectivity Services…" appear to imply that the CA only covers brokered exchange. As we noted in our feedback on the TEF QTF, particularly relative to message delivery and FHIR-based access and exchange, not all exchanges need to be brokered. Current efforts to enable FHIR-based access starts with the actual queries, and after establishing trust, patient discovery, and obtaining endpoints from a directory, is all direct between endpoints. Likewise, message delivery need not be brokered as current case reporting use cases under the Carequality umbrella demonstrate. The EHRA strongly recommends that the TEF CA not make assumptions about the level of brokering that may be utilized, and instead leave that to the TEF QTF to address based on the specific needs and opportunities of the use cases at hand. It furthermore enables TEF to be a framework that reduces the number of point-to-point data sharing agreements that otherwise would be necessary.

The bullet on Responses indicates that a number of parties need not respond, beyond reasons of applicable law. We are concerned that the particular stakeholders, such as Public Health Authorities, certain governmental agencies, as well as Individual Access Service providers, would have data relevant and appropriate to others. Examples include public health data on patients individually or in aggregate that would enable a provider to offer better care for a specific patient or population; a provider being granted access to a patient's data that is maintained by an Individual Access Service; or a consumer/patient obtaining their health data from a governmental agency. We suggest that the basic premise should be that Participants are engaged to enable sharing data with other stakeholders, including patients, who are authorized to access such data unless applicable law prohibits that, or the patient does not consent to such sharing. We suggest the Common Agreement should not add further restrictions, as clarity on how proper authority is asserted and consent is evaluated is defined through the TEF QTF to maximize sharing, reciprocity, and non-discrimination.

Participants and Subparticipants

We appreciate and support the recognition of Participants and Subparticipants that reflect the potential organizations involved in enabling a national network infrastructure.

Required Flow-Down Provisions

We support the need for flow-down provisions and look forward to reviewing the language more specifically once made available for public review.

TEFCA Information and Required Information

We seek clarification as to why ePHI is used to scope Required Information while the Information Blocking rules use EHI. Wherever possible, common scope should be used to define what is minimally required.

Conversely, we must recognize that enabling interoperability not only requires EHI or ePHI, but also other data – including directory data, de-identified data, aggregated data, and other non-health data – which would imply that the Required Information scope should also be larger than ePHI or EHI. This further highlights that caution must be given to defining the scope of Required Information in the TEF CA, rather than through the QTF and SOPs.

In the context of this TEF CA element, we would like to reiterate the importance of not requiring that all information is always exchanged. The use case for each exchange purpose should clarify what constitutes "available" to ensure the intent and spirit of TEF is maintained.

Governing Approach to Exchange Activities under the Common Agreement

We support the general approach outlined to govern updates to the TEF CA, QTF, and SOPs and appreciate all stakeholders are involved and able to contribute.

QHIN Designation and Eligibility Criteria

In our response to the TEF QTF we indicated the importance of reliable performance by the QHIN for the capabilities they provide (e.g., patient discovery). We support addressing this critical element in the TEF CA, in particular the statement: "Demonstrated resources and infrastructure necessary to support a reliable and trusted network." This is critical for all Participants and Subparticipants to establish the necessary expectations and trust not only within their own QHIN, but across the entire TEF.
We want to reiterate the need for a phased approach toward supporting all exchange purposes and their use cases. Having insight into future exchange purposes (e.g., research) would also enable a QHIN to understand what additional exchange use cases they will need to be prepared to enable.

Cooperation and Nondiscrimination

We fully support the notion and need for cooperation and non-discrimination, where for the latter the default approach should be to enable bi-directional, reciprocal interoperability unless the use cases are truly only limited to uni-directional interoperability.

RCE Directory Service

We appreciate the inclusion of a singular directory service that reflects all the relevant QHINs, Participants, and Subparticipants with their official endpoints/addresses for the various purposes that can be used in combination with the QHINs patient discovery services to easily and reliably find the correct endpoints/addresses.

Individual Access Services (IAS)

We understand that QHINs, Participants, and Subparticipants need not provide IAS for individuals, but must be able to respond to IAS requests from another QHIN, Participant, or Subparticipant that is an IAS Provider. The EHRA supports that approach. We do note that there can be use cases in which another Participant or Subparticipant, while not being an IAS Provider, has an appropriate interest in data for a patient they manage that is available through one or more of that patient's IAS Providers. The EHRA suggests that the IAS Provider must respond to those requests by non-IAS Providers where the patient has provided such consent, and according to applicable law. While under FTC that app may be able to not share, we suggest that to participate under TEF they must share. We recognize that the relevant specifications to enable sharing would need to be developed before this capability can be deployed, yet the TEF CA should encourage, if not require, adoption of those capabilities at that time.

Privacy and Security

Privacy and security are critical components when creating a truly trusted exchange framework. As TEF is intended to encompass both HIPAA/42 CFR Part 2 covered entities and non-HIPAA entities, all parties must be held to the same level of secure exchange within the privacy policies across the various jurisdictions and a patient's consent directives, with clear understanding and transparency of how the data is to be used by the connected stakeholders.

Special Requirements (including Consent)

Consent management at scale remains a challenging but important element to enable access to data without a person needing to curate the authorized data set. Standards have been defined on how to tag data and how to assert presence of consents. Adoption is limited, and essential components necessary to have ubiquitous and computable awareness across a network on what data can be shared in accordance with applicable policies across multiple jurisdictions (federal, state, and local) and the patient's consent directives are not available. We suggest that much work needs to happen before this becomes a reality. In the meantime, to comply with applicable law and consumer expectations, it remains important to establish consistent consent management and expectations across all actors in TEF. We encourage RCE to give additional guidance in the following areas:

- Clarify what process will be permitted for capturing and sharing consent. In certain cases, consent may be collected through an intermediary or a third party and presented to the provider or entity holding the patient's record such as can be the case with community providers and the Veterans Administration (VA) or under 42 CFR Part 2 for an emergency physician dealing with a patient in a medical emergency. In other cases, consent must be collected directly from the patient such as in non-medical emergency situations for a 42 CFR Part 2 patient and the disclosure of records by their 42 CFR Part 2 provider to non-Part 2 treating providers.
- Clarify how the requestor is to capture consent compliant with all jurisdictions, as many have specific requirements for the scenarios in which consent is required and the language they must contain.
- Address how consent expiration and revocation by the patient is to be handled.
- Clarify who will take responsibility and liability when a consent is later found to be deficient. Is it the requestor for failing to capture consent properly, or the responder for disclosing PHI inappropriately? If it is the responder, then Participants and Subparticipants may expect to review consent prior to disclosure, which will hamper real-time data exchange.

Fees

We note that where there is bi-directional exchange among parties where both enable an infrastructure to ask and be asked that cost can start to be assumed to be sufficiently distributed to be equitable. However, when access and exchange is unidirectional, there is no such equitable sharing of infrastructure cost. While such a balance would exist in QHIN-QHIN exchanges, that would not necessarily be the case between Participants and Subparticipants within and across QHINs. For example, the benefits determination exchange purpose is mostly uni-directional. We suggest it is clear that appropriate cost-sharing approaches for such use cases remain permitted as currently is allowed by applicable law. If the intent is that all transactions under TEF are free, then other funding methods must

be established for data sources to enable the essential infrastructure to support such exchange purposes and use cases.

Eligibility Criteria

Section 5 of the Draft QHIN Eligibility Criteria references an upcoming SOP that is to describe necessary evidence for required conformance, interoperability, or partner testing. We suggest that for an interested network to be considered a candidate QHIN that network's current performance should be taken into consideration as well – e.g., response times, time-outs, completeness of data, patient matching quality, and consistency across the network, particularly when not deploying an RLS or eMPI for patient discovery. It is important to understand by what measures a network would be considered to be capable of successfully meeting all the criteria that a designated QHIN is expected to meet. We suggest that the service level agreements that have yet to be defined for QHIN performance expectations would be used to identify the relevant performance criteria that should be part of the eligibility criteria.

In this context we also seek clarification on section 2 of the Draft QHIN Eligibility Criteria. This indicates that specialized networks can apply to become a QHIN, and as they do they must provide documentation of information including geography, exchange purposes, and type of information exchanged. It has been our understanding that any QHIN must be able to support all exchange purposes. We want to ensure that section 2 is clear on whether or not there can be specialized QHINs that specialize in specific exchange purposes and use cases.

If a network seeking to become a QHIN is a specialized network, does the request to provide documentation of their specialty indicate the possibility of becoming a specialty QHIN? Or must they address how they will take on all exchange purposes? This would indicate a gap in the application process for the information such a specialized network must provide.

And if so, does that also mean they can only become a provisional QHIN until such time as they can support all exchange purposes and use cases? It has been our understanding that while a specialized network may be a candidate QHIN, a designated QHIN cannot be specialized by any of these characteristics as it must be able to support all agreed to exchange purposes and use cases as they are phased in. We suggest that this is further clarified in section 2.