October 21, 2021

Submitted Electronically

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

RE: Elements of the Common Agreement

Dear Ms. Yeager:

Thank you for the opportunity to provide feedback on the Elements of the Common Agreement that The Sequoia Project created in cooperation with the Office of the National Coordinator for Health Information Technology (ONC). We strongly support the vision of the Trusted Exchange Framework and Common Agreement (TEFCA) as a single on-ramp for seamless health data exchange in healthcare.

Epic has long supported nationwide, vendor-neutral interoperability to connect the healthcare ecosystem. We created Care Everywhere in 2007 to accelerate provider interoperability and expanded our support for information exchange as a founding member of Car*e*quality since 2015. Today, Epic powers health information exchange across the healthcare industry for a variety of use cases, including exchange with health plans, government agencies, and public health authorities.

The Trusted Exchange Framework (TEF) has an opportunity to build on the capabilities of existing health information exchange networks and reinforce key interoperability principles like trust and reciprocity. To help realize this opportunity, we recommend that The Sequoia Project and ONC incorporate the following into the Common Agreement:

1. **A glide path to exchange purposes beyond treatment.** Infrastructure costs, regulatory concerns, and a lack of widely adopted implementation guides for exchange purposes other than treatment will discourage many potential participants from connecting to the TEF via QHINs. We strongly recommend that the TEF should require QHIN support for only treatment and IAS use cases during the first two years of the TEF. The RCE can subsequently add new required exchange purposes gradually as implementation guides are substantiated and adopted. Starting with core exchange purposes like treatment and patient access is also consistent with the statutory requirement to pilot test TEFCA before a widespread rollout.
2. **Mandatory and consistent privacy safeguards implemented by all entities, including Individual Access Service providers.** It is unfair for the privacy and security of patients' sensitive health information to depend on where they live or who holds their data. Patients expect their data to kept confidential and the sale or commoditization of their data might erode their trust in healthcare organizations. Any entity connecting to the TEF should voluntarily commit to complying rules that promote transparency and prohibit inappropriate use, sale, or disclosure of data, even if they are not otherwise required to do so under HIPAA or other applicable law.
3. **Comprehensive reciprocity requirements.** All participants should be required to respond to valid requests for information consistent with applicable law. Requiring reciprocal health information exchange between providers, payers, IAS companies, public health agencies, and other data holders will build trust and goodwill across the network and aligns with both the spirit of Federal information sharing rules and patient expectations that their health information be available to everyone in the healthcare system that needs access to provide care and services.

We look forward to continuing our work with you to expand health information exchange. If you have any questions about our feedback, please don't hesitate to contact us. Thank you for your consideration.

Sincerely,

Rob Klootwyk

Rob Klootwyk
Director, Interoperability
Epic

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Detailed Feedback on the Elements of the Common Agreement

Exchange Purposes

Required Exchange Purposes

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The term Exchange Purposes identifies the reasons for which information could be requested and shared
through QHIN-to-QHIN exchange. Initially, QHINs would support the following Exchange Purposes:
Treatment, Payment, Health Care Operations, Public Health, Benefits Determination, and Individual
Access Services.
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Implementation Guides are Needed to Support Exchange Purposes

We support the aim of expanding health data exchange to use cases beyond Treatment. However, implementation guides (IGs) that adequately address and support the six exchange purposes outlined above have yet to be published and were not included in the QHIN Technical Framework (QTF). Defining IGs for each exchange purpose, including different use cases within a given exchange purpose, is an essential prerequisite to implement additional exchange purposes across a broad network. They include critical guidelines on the set data elements that is appropriate to disclose for each exchange purpose (while complying with HIPAA minimum necessary requirements), which entities can assert specific exchange purposes (and how to express that assertion using OIDs), and confidentiality codes that should be associated with different document types. Other networks like Car*e*quality have published implementation guides for query-based document exchange for the Treatment use case that could be referenced by the QTF.

Without implementation guides for each exchange purpose, healthcare industry stakeholders will be unable to meaningfully participate in the TEF or adopt the TEFCA. Concerns about the infeasibility of ensuring compliance with federal, state, and local privacy rules including HIPAA's minimum necessary requirements when responding to queries without detailed IGs will lead participants to be hesitant to join the TEF. Significant differences in how healthcare organizations interpret federal, and state regulatory requirements will lead to inconsistent implementation and support for non-Treatment/IAS exchange purposes. Consensus-based IGs would create industry alignment on the minimum scope of data necessary to fulfill the needs of a specific use-case and the expected uses and disclosures of that data for that purpose, streamlining information exchange.

Cost Concerns with Multiple Exchange Purposes

Provider organizations, public health authorities, payers, and other classes of Participants and Subparticipants have also been highly sensitive to the infrastructure investment and ongoing storage and maintenance costs associated with increased health information exchange capacity. Concerns about cost will be a major part of organizations' consideration of whether to adopt exchange under the Common Agreement.

Treatment, the most widely adopted exchange purpose in use today, results in networks and healthcare organizations processing billions of transactions each year alone. Facilitating exchange on that scale requires investments in IT infrastructure at participating organizations, in order to ensure performant response times, to store the additional outside data received, and to maintain robust privacy, security, and audit logging capabilities. Networks and their participants also retain staff dedicated to managing the software and infrastructure required for exchange. Requiring the immediate adoption of five additional exchange purposes beyond treatment will result in significant increases in the number of exchange transactions that must be processed and will result in significant, unpredictable increases in the costs that participating entities will bear. This would be exacerbated by the current approach of the QTF, which requires all QHIN-QHIN exchange to flow through a central gateway.

We recommend adopting a staged approach to implementing additional exchange purposes via the Common Agreement. During the initial implementation of TEFCA, QHINs and their Participants/Subparticipants should be required to support exchange for the purposes of Treatment and Individual Access Services. The RCE should work with QHINs, Participants, and Subparticipants on a timeline for the development of IGs and rollout of support for additional use cases. The RCE should accept input on the priority of additional exchange purposes, establish timelines for development and testing of IGs, and establish deadlines for entities to implement support for additional exchange purposes as those IGs become available. Such a process could enable an additional exchange purpose to be adopted network-wide every 24-36 months. A standard process provides a clear and predictable roadmap for additional exchange to TEFCA entities, giving them time to plan additional hardware purchases, develop and test software updates, and implement new operational processes that support the additional exchange purpose.

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Requests

> Only certain QHINs, Participants, or Subparticipants could make requests for each Exchange Purpose. Specifically, a QHIN, Participant, or Subparticipant may only request, Use, or Disclose TEFCA Information for a specific Exchange Purpose if the QHIN, Participant, or Subparticipant is the type of person or entity that is described in the definition of the applicable Exchange Purpose. For example, only a health care provider as described in the definition of Treatment could request information for the Exchange Purpose of Treatment.

We agree that tailoring permissible exchange purposes based on the type of requestor is an appropriate safeguard against inappropriate use or disclosure of information in the TEFCA ecosystem.

Responses

> In most cases, QHINs, Participants, and Subparticipants would be required to respond to a request for certain health information for any of the Exchange Purposes. Responses would not be required by the Common Agreement if providing the information is prohibited by Applicable Law or the Common Agreement. Also, there would be specific exceptions where a response is permitted but not required by the Common Agreement:
>
> - If Signatory is a Public Health Authority;
> - If Signatory is a governmental agency that determines non-health care benefits, including such an agency's agent(s)/contractor(s);
> - If Signatory is a Non-HIPAA Entity provider of Individual Access Services;
> - If the reason asserted for the request is Individual Access Services and the information would not be required to be provided to an Individual pursuant to 45 CFR § 164.524(a)(2), regardless of whether Signatory is a Non-HIPAA Entity, a Covered Entity, or a Business Associate;
> - If the requested information is not Required Information (as described in Section 5 "TEFCA Information and Required Information" below), provided such response would not otherwise violate the terms of this Common Agreement; or
> - If Signatory is a federal agency, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law (e.g., it is Controlled Unclassified Information as defined at 32 CFR Part 2002 and the party requesting it does not comply with the applicable policies and controls that the federal agency adopted to satisfy its requirements).

Reciprocity is a core principle for building trust in health information exchange networks. We recommend that the Common Agreement reflect this important principle by requiring all actors (including Individual Access Service providers and public health authorities) to respond to valid requests for health information unless applicable law or patient preference prevents them from doing so.

Extending the requirement to include Individual Access Service providers will promote greater patient choice by improving the portability of their data if they wish to switch between IAS providers and as patients move between providers in the healthcare system. This expectation aligns with the spirit of the policies advanced under ONC's 21st Century Cures Final Rule and with patient expectations that information they give their care team and in apps that connect to their electronic records will be shared with all their healthcare providers. Because all requesting actors would need to adopt technology that supports the standards for exchange specified in the QTF, requiring actors to respond to requests would not create an unreasonable additional burden.

Required Flow Downs

> Required Flow-Down Provisions. The Common Agreement lays out certain provisions that QHINs would be required to include in their Framework Agreements with Participants and that Participants would be expected to include in their agreements with any Subparticipants. These would be called "Required Flow-Down" provisions. The required flow-down provisions would address: cooperation and nondiscrimination; confidentiality; utilization of the RCE Directory Service; Uses, Disclosures, and responses; Individual Access Services; privacy; security; and other general obligations.

We agree that it is appropriate for the Common Agreement to incorporate required flow-down provisions. Requiring QHINs, Participants, and Subparticipants to have common expectations, especially for privacy, security, and exchange reciprocity, will improve trust and accountability within the network.

TEFCA Information and Required Information

The current definitions for TEFCA Information and Required Information encompass a more expansive dataset than can be exchanged using mature standards today. Although we agree with the principle that an actor should respond with all the information it can reasonably provide to fulfill the request under applicable law, we believe it would be appropriate to define

the scope of data required for exchange under TEFCA in terms of data classes, elements, and formats supported by standards adopted by the QTF for a given exchange purpose. For example, Required Information for the Treatment exchange purpose could be all of a patient's USCDI v1 data exchanged via the C-CDA document format (as specified in the QTF). In another example, Required Information for Quality Improvement within the Health Care Operations exchange purpose could require the data classes supported in a properly formatted QRDA I or QRDA III document.

Defining TEFCA Information and Required Information in a way that refers to standards endorsed by ONC and adopted by the QTF would set clear expectations for actors and leave flexibility within the Common Agreement framework for the adoption of exchange purposes or formats that do not use individually identifiable patient information or other non-health related information like provider directories.

Governance Approach to Exchange Activities Under the Common Agreement

We support the governance approach described in the Elements of the Common Agreement. Establishing a mechanism for QHINs and Participants/Subparticipants to provide input into TEFCA's management, operating procedures, and exchange activities will foster collaboration and a greater sense of responsibility for the network's success.

QHIN Designation and Eligibility

We agree that it is appropriate for the RCE to establish an application process to evaluate prospective QHINs prior to their engagement in exchange via the Common Agreement. However, some of the draft QHIN Eligibility Criteria do not provide clear, objective, and demonstrable criteria that prospective QHINs must meet to achieve designation under the Common Agreement. This will make it more challenging for prospective QHINs navigate the onboarding process and understand the basis for decisions on whether they can achieve designation as a QHIN. Specifically:

- It is unclear how prospective QHINs will demonstrate they are "capable of the exchange" for all exchange purposes. We are not aware of any network that facilitates exchange for all six exchange purposes according to the QTF's specifications at scale, which could result in no prospective QHINs achieving designation. The RCE should instead specify that a prospective QHIN must demonstrate that it can facilitate exchange for at least one permitted purpose at scale according to the specifications of the QTF prior to designation.
- It is unclear whether/how the signatory's existing data sharing agreements, operating policies and procedures, or other related agreements will be evaluated in the context of QHIN designation, including whether certain terms or provisions of those agreements would disqualify an entity from QHIN designation, or whether the modifications will be required for existing exchange agreements outside of the purview of TEFCA.
- It is unclear whether transaction volumes need to exceed a certain threshold to achieve designation.
- It is unclear how contents of audited financial statements will be evaluated in the context of QHIN eligibility, including whether certain positions will be deemed disqualifying if a signatory otherwise meets the requirement to maintain operating reserves.
- It is unclear how the RCE will evaluate whether the organizational structure and staffing are satisfactory for the operation of a QHIN.

The RCE should provide additional details on the demonstrable thresholds or criteria that signatories need to achieve for each of those requirements to promote transparency in the QHIN onboarding process.

RCE Directory Service

We agree that is appropriate to prohibit use of the RCE Directory Service for activities other than to expand or improve connectivity via the Common Agreement.

Individual Access Services

The RCE should clarify that offering a patient portal made available through a healthcare organization's EHR does not constitute providing Individual Access Services under the Common Agreement. As written, it is unclear whether offering a patient portal would constitutes IAS. Today, some patient portals can provide access to data retrieved from outside organizations via FHIR APIs or network-based exchange. However, if a provider offers a patient portal with those capabilities, they may not be able to meet some of the IAS provider requirements, such as the right to data deletion. We do not believe that was the intent of the RCE to define a patient portal as an IAS offering, so we recommend specifying that an IAS Provider

is an entity that is not an EHR-based patient portal that enables an individual to submit requests for information to all QHINs via the Common Agreement.

Robust privacy and security requirements should apply to all IAS providers. This approach would unify the data privacy and security expectations that apply to all handling of the sensitive information that IAS providers and other actors will have access to via TEFCA. The Common Agreement should require all IAS providers to comply with relevant provisions of the HIPAA Privacy and Security Rules, including those that prevent the inappropriate sale, use, or disclosure of patient data. Such a requirement would align with patient expectations that their sensitive health information is private and protected, regardless of the type of entity that possesses it.

Privacy and Security

We support the privacy and security requirements described in the Elements of the Common Agreement, as well as the expectation that they would flow down to all types of Participants and Subparticipants. Patients expect their health information to be protected regardless of whether a particular entity is subject to HIPAA rules. TEFCA should limit the collection, use, and sharing of private information to what is necessary to provide services requested by the patient, with exceptions only for necessary operational activities, similar to HIPAA. It should also include a broad prohibition on inappropriate secondary uses of data, such as commoditization or sale of private information. Patients should not have to navigate divergent opt-out processes for hundreds of organizations or service providers to prevent their data from being monetized.

Consent

We agree with the principle in the Elements of the Common Agreement that consent for exchange should not be needed unless applicable law requires it. The RCE should clarify whether the requestor or discloser of health information is required to collect consent if it is required by applicable law. We believe it the discloser should be responsible, since state or local laws typically restrict the disclosure of health information without consent—not requests for health information. Setting the expectation that the discloser must collect consent (if required) will allow disclosers to ensure that the consent is documented in the form and manner required by applicable law, reducing their risk of liability for impermissible disclosures.

Fees

We recommend publishing the fee schedule for QHINs, Participants, Subparticipants, and other TEFCA entities as soon as possible, since it could play a significant role in the decision-making process for prospective TEFCA actors.

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