Introduction

Thank you for the opportunity to provide feedback on the Qualified Health Information Technical Framework Draft 2 (QTF). We are grateful for the opportunity to collaborate with The Sequoia Project, ONC, and other stakeholders as we collectively work toward a successful implementation of the network envisioned by Congress when it described the Trusted Exchange Framework and Common Agreement in the 21st Century Cures Act.

As you know, Epic is a health IT developer that has substantial experience facilitating interoperable health information exchange between healthcare providers, health plans, apps, individuals, as well as public health, life insurers and other government agencies (such as the SSA) across the country through our interoperable networks that meet industry specific needs such as Care Everywhere, Payer Platform, and Chart Gateway, and our participation in industry-wide initiatives like Carequality. Our technical expertise from supporting exchange on a national scale across a wide variety of stakeholders positions us well to provide the Recognized Coordinating Entity with feedback on how the technical framework of TEFCA can best be implemented to achieve its goal of facilitating a single on-ramp to exchange.

Overall Feedback

Required Exchange Purposes

Draft 2 of the QTF does not provide discretion to QHINs, Participants, and Subparticipants to phase in their participation for all six of the Exchange Purposes. While we strongly support broadening the scope of Exchange Purposes beyond treatment, we are concerned that requiring immediate support of all six Exchange Purposes will deter many healthcare organizations, payers, and other potential Participants and Subparticipants from connecting to a QHIN for the reasons we outline below.

Because the success of TEFCA hinges on voluntary adoption by QHINs, Participants, and Subparticipants, it will be critical to allow Participants and Subparticipants to "ramp up" to Exchange Purposes beyond Treatment. TEFCA could accomplish this by requiring support of the Treatment and Individual Access Services Exchange Purposes at onboarding, and by adopting a publicly available roadmap with timelines for Participants and Subparticipants to implement each additional use case. The roadmap should account for the time needed to establish clear implementation guides for each use case, QHIN/Participant/Subparticipant resource constraints, and outstanding legal and compliance concerns needing resolution. This will promote rapid adoption of the Common Agreement, while ensuring the TEF drives progress towards expanded exchange across all six Exchange Purposes.

Concerns Related to Immediate Support of All Exchange Purposes

Our experience attempting to expand exchange beyond the treatment use case has been that the following will be barriers to adoption.

1. Unpredictable and Potentially Substantial Infrastructure Cost and Capacity.

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

Requiring the immediate adoption of five additional exchange purposes beyond treatment will result in significant increases in the amount of exchange transactions that must be processed and could result in unpredictable but significant increases in the costs that participating entities will bear. Networks and healthcare organizations participating in health information exchange today process billions of transactions each year for the treatment use case alone. Facilitating exchange on that scale requires massive investments in IT infrastructure at participating organizations to ensure highly 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, infrastructure, and compliance required for exchange.

2. Legal Hurdles.

Significant differences in interpretation of federal and state regulatory requirements exist across healthcare organizations. We have recently experienced this firsthand in our efforts to facilitate increased exchange for public health purposes in response to the COVID-19 pandemic. For example, Public Health Authorities do not agree on what constitutes the "minimum

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necessary" health information under HIPAA for their surveillance and pandemic response activities. In addition, state laws place further and varying restrictions on the use and disclosure of health information for public health purposes.

Use cases beyond Treatment require intensive analysis by Participants and Subparticipants to identify the minimum necessary health information needed to fulfill a request, and to ensure that requests are answered in a manner that complies with a myriad of federal, state, and local privacy expectations. Harmonizing those complex obligations via the QTF will require extensive and broad collaboration amongst industry stakeholders.

While the Common Agreement will be a step in the right direction toward adoption of exchange for more use cases by setting baseline expectations once exchange takes place, it does not eliminate the obligations of network entities to comply with applicable federal, state, and local law. Many prospective Participants and Subparticipants will be concerned about their ability to comply with both applicable law and their obligations under the Common Agreement and is likely to make Participants hesitant to join the network.

3. Technical Barriers.

The Draft QTF does not differentiate between use cases and does not reference use case specific Implementation Guides in the standards it adopts for exchange. While these standards have robust adoption and have been proven effective for the treatment use case, the same has not been demonstrated to be true for other Exchange Purposes contemplated by the Common Agreement. The obligation to adhere to the HIPAA minimum necessary standard, and the differences in content and format needs across use cases will vary for each Exchange Purpose. For example, the C-CDA implementation guide for electronic case reporting (eCR) is different from the C-CDA templates typically exchanged for treatment and is tailored to the content needed for that use case. Similarly, the appropriate data set and format for exchange for quality measurement and improvement will differ from the dataset needed for population health management—despite both ostensibly falling under the *Health Care Operations* Exchange Purpose.

The industry has not previously addressed this barrier in a unified manner, so determining the optimal approach will require extensive collaboration across industry stakeholders. Ultimately, the QTF will need to specify use case specific Implementation Guides to which entities must adhere for each Exchange Purpose to alleviate concerns related to the minimum necessary requirement of HIPAA, and to create a single on-ramp that serves each entity joining the Trusted Exchange Framework according to its needs. Those Implementation Guides will need to be available as a prerequisite for QHINs, Participants, and Subparticipants onboarding to those exchange purposes.

Feedback on QHIN Exchange Scenarios

Query Scenarios

Requirement to Query All Participants for Every Patient Lookup Request

The QTF states the expectation that each QHIN would have "either a Record Locator Service (RLS) OR Enterprise Master Patient Index (eMPI) OR the ability to query all of its Participants for a patient lookup within the timeout limitation as specified in the QHIN Service Level Requirements Policy."

We agree that the capability to conduct a query of all TEF entities would represent a powerful tool for patients to direct their own care, and for providers to have a complete picture of patients' conditions when treating them. We are concerned, however, that the industry is not prepared to support the full-scale use of these "broadcast queries" in a manner that is cost efficient and does not result in poorly performing response times.

In the U.S., there are more than 3.4 million scheduled patient encounters per day, and 500,000 unplanned encounters, all of which would potentially elect to conduct broadcast queries for EHI for treatment purposes. If this were the case, each endpoint in the QHIN Exchange network could need to respond to nearly 4 million patient discovery queries each day. This does not include additional requests for broadcast queries that would originate from payers, public health agencies, and other actors such as individuals for the other five Exchange Purposes. We anticipate that the volume of those requests would be similarly substantial. The sheer volume of patient discovery queries (as many as 1.4 billion per year for treatment alone, according to the previous figures) would require increases in server capacity that would be cost prohibitive.

The QTF should remove its expectation QHINs to query all of its participants for every exchange request in favor, and instead allow QHINs to target "smart queries" to its Participants and Subparticipants that are most likely to hold the health information the requestor seeks. In the execution of a smart query, entities would be able to conduct a query that algorithmically targets multiple participants in the QHIN Exchange Network that have a high probability of containing the EHI

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they seek. For example, a smart query could use geolocation to target organizations based on a patients' home and work addresses. The QTF should include smart queries as an incremental step towards a true broadcast query until mature standards to conduct broadcast queries allow for efficient scalability, or participating QHINs agree that such queries can be supported without significant performance concerns. Smart queries could also reduce duplicative requests by declining to re-query the same endpoint more than once in a given period (i.e., declining to re-query the same clinic within 15 or 30 days of the previous query to avoid repeated fruitless queries).

Requirement to Combine Participant and Subparticipant Responses into a Single QHIN-Level Response

The Patient Discovery and Document Retrieval flows state an expectation that QHINs must combine the responses of their Participants and Subparticipants into a single response that is transmitted back to the Query Source. This could result in end users not receiving information in a timely manner. Requiring the aggregation of results from each QHIN for response in a single transaction will force queries to move at the pace of the slowest respondent at each step. Responding QHINs will need to wait for a response from its slowest Participant before responding to the requesting QHIN, and the requesting QHIN will need to wait for the slowest responding QHIN to respond before transmitting any EHI to the Participant. If a QHIN, Participant, or Subparticipant is experiencing an outage, the request will need to time out at each step before returning information to the requestor. In the case of a query for treatment purposes (especially in emergency situations), this delay in access to information would introduce patient safety risks.

The QTF should not be prescriptive in which entity ultimately responds to the requestor. Rather, the QTF should require that QHINs are able to facilitate response of its Participants to queries. Some QHINs may find it advantageous to take the approach of operating a single gateway through which their Participants' responses are returned to the requestor. These QHINs and their Participants might find this single hub approach more straightforward for connection management. Others might adopt a federated approach where the QHIN directs the query directly to its Participants, who are then responsible for returning a response to the requestor directly. Existing federated networks have demonstrated that these approaches can coexist and seamlessly exchange data within a network of networks.

Patient Discovery

Alternate Flow 2: Query Source Asserts an Instance Access Consent Policy or Access Consent Policy

This flow appears to envision that a Query Source could assert that it has a patient's signed consent before it initiated a query for their records from outside sources. However, consent must meet the requirements of the disclosing organization, which will base its requirements and consent form on state and local law—not the querying organization. Therefore, it will be infeasible for a Query Source to assert that it has a patient's consent to the disclosing organization. We recommend modifying this flow to reflect that the Query Source will need to have information about the disclosing organization's consent policy before it can assert that it has met the consent policy. Alternatively, Trusted Exchange Framework could specify a network-wide consent policy to avoid the need to account for the idiosyncrasies of jurisdictions across the United States during query requests.

Scalability

We recommend requiring all QHINs to support asynchronous XCA. It has been supported in productions systems for several years, and yields significant improvements in network scalability.

Message Delivery (Push) Scenarios

The RCE solicits feedback on whether to include QHIN Message Delivery as a requirement in the QTF, including whether it could be included as optional. Making it optional would contribute to a fragmented experience for Participants and Subparticipants, since some QHINs will implement it while others will not.

XCDR does not have broad adoption in the industry today for message delivery workflows. Because of its lack of adoption, prospective QHINs, Participants, and Subparticipants would need to update their technology to support the XCDR standard—increasing the costs and burden associated with joining the Trusted Exchange Framework. Additionally, the lack of use of the XCDR standard at scale today introduces the risk associated with deploying it for use at scale for the first time as part of the Trusted Exchange Framework.

While the potential downside associated with requiring Message Delivery in the Trusted Exchange Framework could outweighs the potential benefits, the Trusted Exchange Framework could still help improve push-based exchange by publishing a centrally maintained directory of network Participants and Subparticipants. Maintaining a directory would

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improve the reliability of push-based exchange across communities without requiring the adoption of a new standard for exchange. It would also complete a prerequisite to adding XCDR support in a future version of the QTF.

Feedback on Requirements for Functions and Technology to Support Exchange

Patient Discovery Query

Additional Recommended Requirement

We recommend including a requirement that a Responding QHINs include faithful representations of the demographics data in the responder's system for each Patient Discovery Match (i.e., respondents should not be permitted to mirror back the demographics used to initiate the Patient Discovery Query). This will improve patient matching integrity by allowing the Query Source to conduct further analysis on the demographics data returned to them to evaluate whether a positive response represents a match with a probability that satisfies its own thresholds to establish a match.

Document Query and Retrieve

Exchange Format (QTF-039, QTF-040, QTF-043)

QTF-039 sets the expectation that all XCA responses be converted to C-CDA 2.1 documents if they are not already in that format. While we agree that C-CDA 2.1 formatted documents are typically the most appropriate way to exchange most types of discrete clinical data, it would not be possible to convert some clinical data that is routinely exchanged today to that format (for example, images).

While QTF-040 and QTF-043 appears to provide some flexibility to respond with documents in other formats if requested, we recommend clarifying the data classes and use cases for which that would be appropriate to promote consistent implementation. For example, for what use cases or data classes would QTF-043 permit binary responses? What specific data classes or data elements should be converted to fit the C-CDA 2.1 document format? Without clarifying these expectations, the fidelity of data exchanged via QHINs could be reduced since QHINs may mistakenly convert data to the C-CDA 2.1 document format that could be more robustly expressed in a permissible alternative format.

Patient Identity Resolution

Service Level Agreements (QTF-067)

While it is generally reasonable to expect QHINs to perform to the standard described in an agreed-upon service-level agreement, we note that a draft SLA for patient identity resolution has not yet been published. The RCE should prioritize publishing proposed terms of any SLA requirements related to technical functions so that prospective QHINs can investigate, design, develop, and deploy updates that might be needed to its infrastructure to meet the SLA's expectations.

Testing Procedure Supporting Requirements

Test data in Production Systems (QTF-095, QTF-096, QTF-097)

Building fictional records for test patients and test clinicians in a production system increases the risk of accidental exchange of fictional information which increases the risk of inappropriate disclosures, data integrity issues, and to patient safety. Given that QTF-095 requires all QHINs to create and maintain a test instance of their QHIN system, we expect that a sufficiently robust test infrastructure would exist network-wide, eliminating the need to create test records in production systems. Additionally, because QTF-097 prohibits registration of test data into the production RCE Directory Service, it is unclear whether fictional records in a production system could be used to test connectivity and exchange workflows. We recommend removing the expectation that QHINs create fictional test records for patients and clinicians in production environments from QTF-096.

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