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RE: Trusted Exchange Framework: Recognized Coordinating Entity – QHIN Technical Framework Draft 2, July 26, 2021

Submitted electronically to: https://rce.sequoiaproject.org/qtf-feedback/

Dear Mrs. Yeager:

On behalf of Cerner, I am writing to provide input to the QHIN Technical Framework Draft 2 (QTF) in support of the Trusted Exchange Framework initiative under the 21st Century Cures Act. Cerner has provided feedback and participated in various listening and discussion sessions on the Trusted Exchange Framework (TEF), Cooperative Agreement (CA), and QHIN Technical Framework (QTF) to date and would like to provide further feedback on the latest QTF draft in light of the goal to formally start the implementation of a trusted exchange framework in 2022.

We offer the following five main considerations to further shape the QTF to be a practical, and implementable starting point that builds on the experiences of the current national network that has emerged and works.

Record Location – Method and Performance
When Cerner co-founded CommonWell, one of the key drivers was to enable record location at a national level enabling providers to find their patients' information across the hundreds of thousands of provider organizations and potentially other health and health care entities. It is vitally important that any network can efficiently maintain and be an effective reference resource for those relevant locations to query for data, or notify as needed for a given patient, without having to ping everybody always. In that context, it is important to recognize that the function of a record locator service (RLS) is vitally important to a network, and across collaborating networks. This could be implemented in a variety of ways such as brokered, federated, centralized, or decentralized.

We therefore understand the flexibility implied in the QTF to not just require a RLS or Enterprise Master Patient Index (eMPI), but allow for a choice of techniques as well, as long as certain Service Level Agreements (SLAs) are met. The QTF focuses on QHIN to QHIN SLAs, but the QTF has not clearly defined those. We suggest that these SLAs must not only include performance objectives, e.g., <3 second response time to get matches, locations, endpoints/addresses, but also the quality of the matches, locations and endpoints/addresses (i.e., does one receive all matching patients and their locations, thus reducing the completeness of the record, or too many, where the patient actually ends up not having records, or fewer due

to variances in matching logic and accessibility of endpoint thus not having the full set). Without such QHIN assurances, those connected to the QHINs will have an increased risk of user experience, efficiencies, and effectiveness challenges.

We suggest that until these SLAs are defined, networks should not become designated QHINs to ensure they meet and have demonstrated the minimum expectations upfront. Removal of a QHIN that cannot satisfy these requirements will not only impact their participants, but also other QHIN's participants.

These concerns particularly apply to those networks contemplating to become a QHIN that do not utilize an RLS and/or eMPI. As the text indicates on page 8 (highlight is ours): "Each QHIN has 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**". This technique would allow a QHIN to query all their endpoints every time a request is made to find potential matches and locations. Considering network connectivity, variability in endpoint system performance and matching approach/quality, this could yield to unpredictable response times and completeness of the response. Candidate QHINs should be very clear about the expected performance to enable them to make the appropriate architectural decisions to provide consistent, high-performance responses to record location and patient matching.

In this context we note an additional challenge with Alternate Flow 3, where the QHIN dynamically queries all their endpoints for patient discovery every time the QHIN is being queried for patient discovery. As this method has a higher risk of uneven performance of such a QHIN over time due to potential varying system availability, performance, algorithms, etc., that may not be fully transparent to the query source. One may then start to use Alternate Flow 1, though not expected to be widespread, to aid in obtaining such transparency, which should not be an unintended consequence of permitting a QHIN to not have a more robust, predictable patient discovery method. This further emphasizes the need for clearly defined performance criteria including reporting on unfound patient records due to response time, timeouts, variability in algorithms, etc., where dynamic queries are deployed supporting patient discovery that can help mitigate such unintended consequences.

We look forward to review and respond to actual SLAs being proposed and finalized that set a proper bar without diluting the quality and performance of participating QHINs.

Record Location - Broadcast Queries

We note that for record location, Alternate Flow 1 leaves room for utilizing "broadcast" queries to far more endpoints than is reasonable when the likely location(s) are not known to the requester as there is no upper limit to the number of organizations to include. Alternate Flow 1 effectively enables a widely cast query to hundreds/thousands of endpoints directly. Such broadcasting is going to create challenges as this bypasses the intent of QHINs to orchestrate that process. We recognize that a specific upper limit is challenging. We suggest clarifying that Alternate Flow 1 is only meant for a small number of targeted organizations with high likelihood of finding patient data. We also suggest permitting the responding QHIN to decline responding to a specific Alternate Flow 1 query when the request is unreasonably large and the Nominal Flow would have been a better fit, or converting the query to a Nominal Flow query according to clearly documented criteria.

Patient Matching
We recognize the challenges with patient matching to enable QHINs to find "all" matching patients and their locations. However, we believe the bar being considered of not having a minimum level of patient matching alignment with common, predefined criteria and SLAs has a high risk of undermining the trust in a trusted exchange framework. We suggest that minimum matching criteria/algorithm requirements are set from the onset that can be progressively improved on as suitable unique identifiers and matching criteria continue to evolve.

Reformatting Documents
The QTF states in the Document Query and Retrieve section "IHE does not define a document beyond *"a collection of bytes, including proprietary and textual formats."*[1] *Therefore an XCA document may be any form of information including C-CDA 2.1, FHIR® resources, PDF, or other formats. For purposes of Document Query and Retrieve, C-CDA 2.1 is the expected format for all patient information. If a Responding Source is unable to return a C-CDA 2.1 document, the data is converted to the C-CDA 2.1 format by a Responding QHIN, Participant, or Subparticipant prior to transmission to the Initiating QHIN."* QTF-039 further clarifies this to mean *"If a Document Retrieve response is not in C-CDA 2.1 format, QHINs MUST convert the response to C-CDA 2.1 format except where consistent with QTF-043 and QTF-040".*

While QTF-40 and QTF-43 provides clarity on exceptions, we are very concerned with QTF-039 and strongly urge removal of this requirement. We do not find that it is appropriate for the QHIN to open and change any document that passes through it or is transacted under a trusted exchange framework. The QHIN should at most broker and facilitate the query and delivery of a document as provided by the source. Looking forward as well to likely FHIR based access and exchange that involve documents, we note that brokering should also not be a given as documents are anticipated to be shared directly between participants within and across QHINs under a trusted exchange framework both early on, and likely for many use cases.

Creation of what is effectively a copy of the original document yields a number of challenges and concerns:

- Privacy and security concerns as data is being managed in more places than necessary.
- Increased number of documents containing the same data will increase challenges in de-duplication and reconciliation by the recipients.
- Many documents are hard to convert without loss of information and/or changes in information (local or older vocabulary transformations that may not be feasible – e.g., too many local varieties to accommodate - or represent different levels of granularity, variant data structures, etc.) or where a more current representation, e.g., FHIR Document, would have to be converted back to CDA C-CDA R2.1.

Rather, we suggest that QHINs be capable of sharing and exchanging documents of any type in their original state and instead focus on participants to generate new documents in accordance with the latest standards adopted in ONC's certification program or other well recognized document formats (e.g., those used for case reporting and registry reporting). Participants

[1] *IHE IT Infrastructure White Paper Health Information Exchange: Enabling Document Sharing Using IHE Profiles*– available at https://www.ihe.net/Technical_Framework/upload/IHE_ITI_White-Paper_Enabling-doc-sharing-through-IHE-Profiles_Rev10_2012-01-24.pdf

should be required to accept older document formats and at least enable viewing of those documents, a method that is widely supported through ONC's HIT certification program.

Message Delivery

The request for comments specifically asks for feedback on three options to progress with message delivery. In response to earlier QTF drafts, we expressed concern with the consideration of XCDR as a QHIN-to-QHIN message delivery mechanism as its adoption is very limited if not non-existent, and it does not enable the types of use cases where delivery needs to be directed to a specific individual or entity within a (sub)participant's organization. Investment in capabilities using an older, insufficient standard is unnecessary and raises the cost of the TEF with an added risk of some requirements being propagated to (sub)participants to enable QHINs to manage message delivery. In this context, we recommend starting with option two to not introduce XCDR. We do want to offer an alternative to waiting for FHIR only that option 2 proposes enabling the TEF to support message delivery from the start.

We suggest that the QTF should optionally allow for support of already widely adopted message delivery suitable to the use case at hand. Specifically, support for Direct based messaging would provide a number of benefits

> Direct is a widely supported protocol with a mature infrastructure enabling communication of a variety of payloads, although mostly documents, to specific individuals or organizations.
>
> This capability has already been deployed for point-to-point interaction, as well as under the legal framework of Carequality, a model for cross QHIN communications, for electronic case reporting.
>
> Direct effectively provides a consistent base method within, across, and outside networks.

Optional support of Direct with specific support for record location services, endpoint discovery, and aligned address directories across QHINs can go a long way to filling message delivery gaps currently experienced while allowing FHIR to mature to complement or replace it as an appropriate directed push method. The TEF CA would provide substantial value without a need to broker message delivery as it would allow for consideration of other widely available methods (in this case the ability to use either Direct or XDR to deliver case reports directly to APHL under the TEF as currently possible under Carequality).

We want to emphasize in this context that QHINs need not only enable brokered data access and exchange, as Carequality already has successfully demonstrated, but also unbrokered access and exchange. While the premise of brokering is understandable and perhaps natural for the document exchange use case and is widely deployed, not all communications necessarily benefit from that. In fact, we note that the primary value of a QHIN actually is:

> As a record locator services with high-quality patient matching to know where there is data, or potential need for data, of a patient
>
> As a legal framework that avoids point-to-point data access and exchange agreements for defined purposes.

As the FHIR deployment timeline is unfolding, and likely to require a number of years to go beyond queries to be widely deployed, it further underscores the value of advancing Direct under a common legal framework with extensive directories of Direct addresses that can further take advantage of record locater services to deliver messages to the right and most likely interested stakeholders.

Thus TEF, CA and QTF as a consequence, should not be based on a premise of brokered communication only, and therefore able to adopt well established message delivery messages from the start rather than waiting for FHIR based push methods having matured to deploy under TEF.

FHIR Roadmap
Regarding the request for input on a FHIR roadmap for the QTF, we encourage the RCE to closely follow the efforts across CommonWell, eHealth Exchange and Carequality, in collaboration with FAST, to FHIR enable national network level, scalable deployment of FHIR beyond document exchange only, with or without brokering intermediaries for some or all of the necessary infrastructure.

The initial focus in those efforts is on establishing a trust fabric (authorization, authentication, registration) that can co-exist within and across networks, and then on deploying support for HL7 FHIR R4 US Core queries. Subsequent phases would address other use cases that will go beyond queries that may start to address some of the message delivery uses of interest, such as those being focused on by HL7 Accelerators, e.g., Argonaut, Da Vinci, CARIN, or others, as well. Once the initial capabilities are sufficiently mature, the QTF should be updated to incorporate these capabilities with the lessons learned.

Please do not hesitate to contact us if we can be of further assistance.

Sincerely,

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