

September 17, 2021

ONC TEFCA Recognized Coordinating Entity Mariann Yeager Chief Executive Officer The Sequoia Project 8300 Boone Boulevard Vienna, Virginia 22182

Micky Tripathi, PhD, MPP National Coordinator for Health Information Technology Office of the National Coordinator for Health Information Technology (ONC) U.S. Department of Health and Human Services 330 C Street S.W. Washington, DC 20201

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

RE: Draft Qualified Health Information Network (QHIN) Technical Framework (QTF)

Dear National Coordinator Tripathi and Ms. Yeager:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the Draft Qualified Health Information Network (QHIN) Technical Framework (QTF). HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

Overall, we applaud the publication of the draft QTF, recognizing its significance in advancing interoperable health care in the U.S. and "strong privacy and security steps, approaches for identifying and authenticating exchange participants, conducting patient discovery and identity resolution, as well as support for required exchange protocols."

HL7 comments on relevant portions of the draft QTF are below, reflecting the perspectives of our Work Groups, Accelerators, and Policy Advisory Committee. Also, given the draft QTF's spotlight on HL7 FHIR®, we offer our perspectives and reaffirm HL7's commitment to work individually and in tandem with our federal government partners to advance these critical issues. Regarding what elements should be included in a TEFCA FHIR Roadmap and for enabling FHIR data to be used by Health I'T systems for the purposes outlined in the draft QTF, HL7 stands ready to practically and meaningfully contribute to and facilitate help with feedback on the TEFCA FHIR roadmap. This includes insight about the various ways that HL7 FHIR can be used in the TEFCA context.

Should you have any questions about the attached, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC and the ONC TEFCA Recognized Coordinating Entity

Sincerely,

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Charles Jaffe, MD, PhD Chief Executive Officer Health Level Seven International

Walter G. Suarez, MD, MPH Board of Directors, Chair Health Level Seven International

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

Below are HL7's comments on the Draft Qualified Health Information Network (QHIN) Technical Framework (QTF).

Draft QTF	HL7 Comments
Feedback Regarding Definitions	No comment
Feedback Regarding QHIN Exchange Scenarios for Query	 Patient Matching HL7 notes that there are no defined matching criteria and/or algorithms defined for QHIN-to-QHIN interactions. We strongly urge that appropriate minimum criteria and standards are established to enable consistent and predictable expectations to find all of a patient's data across QHINs. Document Reformatting Requirement The QTF Draft 2 specifies that QHINs implement the IHE XCA profile to enable query-based network-to network document exchange. HL7 has the following comments: The Draft QTF states that "If a Document Retrieve response is not in C-CDA 2.1 format, QHINs MUST convert the response to 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." For reference: QTF-040 Responding QHINs SHOULD transmit any specific document format requests (provided by the Initiating QHIN via the IHE XDSDocumentEntryFormatCode XCA parameter) to Responding Sources. QTF-043 - Responding QHINs MAY provide patient information in other document format is requested by the Initiating QHIN via the IHE XDSDocumentEntryFormatCode XCA parameter, or where C-CDA 2.1 format documents are inappropriate for the content (e.g., Public Health submissions or Payer claim/coverage documents).
	formats across participants, we are concerned that this requirement

Draft QTF	HL7 Comments
	creates undue burden implementing conversion capabilities where it is reasonable to expect that receivers can manage (view, process) older formats, if not newer formats (e.g., HL7 FHIR Documents). Conversion of older versions may be challenging, as there may not be enough data to yield a properly conformant CDA C-CDA 2.1 document. Merely wrapping it as an unstructured document would not yield additional value either. Rather HL7 suggests that TEF focuses on promoting and driving that any newly generated documents adhere to the most current standard adopted for certification, which currently is CDA C-CDA 2.1, plus referenced companion guidance and may in the near future start to include an HL7 FHIR Document format. This approach has added benefits of better enabling other future standards version advancement.
Feedback Regarding QHIN Exchange Scenarios for Message Delivery	• HL7 recognizes the value of enabling message delivery under TEF. We note that adoption of XCDR is extremely limited, adding an additional standard to the stack would significantly increase complexity, that there is wide support for Direct as an alternative, and that use of XCDR would be temporary because HL7 FHIR adoption and implementation is progressing rapidly in multiple scenarios. Therefore, it is prudent not to require XCDR. The RCE should consider that Direct could be used already where QHINs can provide substantial value in directory services to find and address organizations and individuals alike within, across, and outside networks.
	• HL7 notes that for the Public Health use case of case reporting, the Carequality framework has already enabled such an approach where the eCR Now on FHIR methodusing an HL7 FHIR based SMART App to trigger data collection using FHIR based APIs, then generating a CDA eICR document that is delivered directly to APHL using either XDR or Direct primarily takes advantage of the Carequality trust framework.
	• Similar to our feedback on the FHIR Roadmap, HL7 suggests that message delivery need not require a brokering approach, as the Direct or HL7 FHIR based methods do not require such additional overhead. Optional adoption of Direct that focuses on directory services may be a reasonable progression as HL7 FHIR matures, and/or use of XDR for certain use cases as demonstrated by the case reporting example.

Draft QTF	HL7 Comments
Feedback Regarding Functions and Technology to Support Exchange	No comment
Feedback Regarding Constraints for Participants and Sub-participants	 HL7 has a series of foundational questions regarding constraints for participants and sub-participants. These include: Is TEFCA, and specifically are the QHINs, required or expected to support HL7 FHIR-based API exchanges? If so, when and in what sequence for different functions or use cases? Would participants and sub-participants WITHIN a QHIN be able to conduct health information exchanges/controlled access to health information via HL7 FHIR-based APIs? Would a participant/sub-participant in one QHIN be able to conduct exchanges with a participant/sub-participant from ANOTHER QHIN using HL7 FHIR-based APIs? Using QHIN trust framework, directory, and RLS only; Using QHIN(s) as a message broker in the middle. What are the use cases when QHINs may be expected to support QHIN-to-QHIN FHIR-based exchanges?
Other Feedback	No comment
Should the QTF include QHIN Message Delivery? If so, how should it technically be specified?	 Regarding the question of if the QTF should include QHIN Message Delivery, HL7 observes that since Message Delivery is a part of the current landscape, we do not see how it could not be supported at all. The critical question is <u>how</u> QHIN Message Delivery could be supported. Please also see our comments on <i>"Feedback Regarding QHIN Exchange Scenarios for Message Delivery"</i> above. HL7 inquires what the reasons are for not considering integration of Direct Messaging in the initial QTF. HL7 also asks how the risks and costs versus the benefits are viewed of introducing a new set of standards in XCDR that will be only temporary by design?

Draft QTF

What elements should be included in a TEFCA FHIR Roadmap to provide predictability and a clear direction for QHIN-to-QHIN exchange regarding the implementation of FHIR for QHIN Query, QHIN Message Delivery and for enabling FHIR data to be used by Health IT systems?

HL7 Comments

Overarching FHIR Roadmap Comments

• Regarding what elements should be included in a TEFCA FHIR Roadmap and for enabling FHIR date to be used by Health IT systems for the purposes outlined here, HL7 stands ready to practically and meaningfully contribute to and facilitate help with feedback on the TEFCA FHIR roadmap. This includes insight about the various ways that HL7 FHIR can be used in the TEFCA context.

Detailed FHIR Roadmap Comments

HL7 appreciates the inclusion of a FHIR Roadmap in the Draft QTF, while the initial focus is on IHE based Document Exchange. Two key issues that can be considered in the Roadmap include:

• Use of FHIR based document exchange to migrate document exchange from IHE profile based to FHIR based.

HL7 FHIR Implementation Guides (IGs) and profiles are already available to enable this inclusion earlier on a Roadmap, particularly considering these capabilities already have been deployed. HL7 stands ready to gather a master list of relevant and user-ready IGs and profiles for this purpose.

• Use of FHIR based data exchange such as queries to USCDI/EHI using FHIR US Core.

TEF provides a valuable opportunity to scale national level trust, access, and exchange based on FHIR. Many of the HL7 FHIR accelerator use cases lend themselves to be adopted at some point under TEF. HL7 offers the following considerations to incorporate those into a Roadmap:

• The current QTF is exclusively based on a brokering model where all transactions flow through a QHIN. HL7 suggests that for many FHIR based use cases this is not necessarily required or beneficial and therefore should not be an a priori, cross-use case requirement. The value of the TEF for many of these use cases is in the trust fabric that TEF provides, the record locator (RLS), master patient index (MPI), and endpoint discovery processes. HL7 recommends that the FHIR Roadmap should recognize this need and not require brokered-only FHIR based use cases. It is important that the QTF

Draft QTF	HL7 Comments
	 can be used for trust, record location, end point discovery, authorization, authentication and registration (as currently being pursued by the Carequality FHIR implementation Guide) while letting individual QHINs determine when and how much to broker beyond that. As implementation experiences mature, appropriate use of brokered approaches will emerge. From a use case deployment perspective, HL7 suggests that the initial focus should be on FHIR US Core to establish the foundational elements, and grow the use cases based on initial deployment experiences and priority.