



June 17, 2019

Submitted electronically

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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Trusted Exchange Framework, the Minimum Required Terms and Conditions, and the QHIN Technical Framework of the Common Agreement

Dear Dr. Rucker:

Thank you for this opportunity to provide comments on ONC's second draft of the Trusted Exchange Framework, the Minimum Required Terms and Conditions, and the QHIN Technical Framework of the Common Agreement.

We support the intent behind these provisions and appreciate ONC's updates to the initial draft. Below, we have provided an executive summary of our comments followed by detailed input. Our comments draw from our experience supporting hundreds of thousands of clinicians in exchanging millions of patient records per day with each other as well as clinicians using other vendors' software, HIEs, industry frameworks such as Carequality, and government agencies such as the Social Security Administration.

We hope that our attached feedback helps guide ONC to structure a final set of provisions that will expand and simplify interoperability, promote innovation, and reduce costs.

We are happy to answer any questions you may have about our comments. Thank you for your consideration.

A handwritten signature in black ink that reads "Judith R. Faulkner".

Judith R. Faulkner
CEO
Epic Systems Corporation



EXECUTIVE SUMMARY

Epic appreciates ONC's updates to the first draft. This new version needs two key changes:

1) Protect healthcare providers from massive cost increases for interoperability by allowing QHINs to use their preferred exchange models.

The majority of U.S. healthcare providers will face a stark choice under the Common Agreement – remain outside the Trusted Exchange Framework, or suffer financial harm from high startup and ongoing maintenance costs passed down from the QHINs.

This is because the Common Agreement requires QHINs to use a centralized exchange model. This model requires large upfront investments such as data center and hardware infrastructure and has high ongoing costs including staff, storage, and security. These costs will fall on the users. Most of the centralized exchange models failed in the U.S. because of these high costs, which the users did not want to bear especially because less expensive, capable methods were available.

Most U.S. healthcare providers use HINs with federated or other non-centralized models. These models are much less complex to set up and maintain and almost always cost the healthcare providers much less to use. They have also been proven to share data successfully with the HINs that do use centralized models.

ONC should update the Common Agreement to allow a “model-agnostic” approach. This will allow the HINs that serve the majority of U.S. healthcare providers to become QHINs and continue to offer cost-effective interoperability. HINs that have centralized models can keep them. Providers that are not yet connected to HINs can choose the model they prefer.

2) Add a pilot phase to avoid interoperability disruptions during rollout.

Broadcast queries and other new requirements have never been deployed at scale in the industry. Giving hundreds of thousands of providers access to these capabilities for the first time, at the same time, may disrupt interoperability during rollout.

Congress has mandated pilot testing for new requirements.¹ ONC should update the Common Agreement accordingly.

We remain committed to assisting ONC in developing provisions that achieve our common goal of expanding and simplifying interoperability for all Americans.

¹ Refer to Section 4003(b)(9)(B)(iii) of the 21st Century Cures Act



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Minimum Required Terms and Conditions

Definitions

Section 1

2015 Edition

The TEF, MRTCs, and QTF did not reference the 2015 Edition. ONC should remove the definition.

If not removed, the definition needs clarification. In its NPRM to implement provisions of the 21st Century Cures Act (21st CC NPRM) issued in February of 2019², ONC proposed numerous modifications to the 2015 Edition with compliance deadlines varying by requirement. In our comments on that NPRM, we urged ONC to adopt a clearer naming convention that allows stakeholders to understand which of the updated criteria and requirements health IT developers are compliant with. We recommended the following naming scheme:

- Changes to certification made upon publication of the final rule be versioned as **ONC 2015 1.1 Edition**.
- Changes to certification made effective upon 1/1/2020 (e.g., NCPDP SCRIPT 20170717) be versioned as **ONC 2015 1.2 Edition**.
- Changes to certification made effective 24 months after the publication of the rule (e.g., updates to data export) be versioned as **ONC 2015 2.0 Edition**.

ONC's inclusion of USCDI, a 2015 Edition Certification criterion, in the MRTCs is an example of why version clarity will be needed for health IT stakeholders. ONC should clarify which of the above "versions" of 2015 Edition certification requirements the MRTCs reference.

Electronic Health Information

ONC should reference the definition of EHI that is used in the Code of Federal Regulations to ensure that the definition aligns across federal programs.

We agree with ONC's decision to require that QHINs, Participants, and Participant Members exchange EHI in the "then current USCDI."

Information Blocking

Information blocking is not referenced in the TEF or Common Agreement. ONC should remove the definition.

QHIN Application Process and Onboarding

Definitions (Section 1)

Cohort and Cohort Deadline

ONC should remove the step that requires Provisional QHINs to be assigned to a Cohort with an associated Cohort Deadline. ONC acknowledges that existing HINs will have varying degrees of readiness to meet the QHIN onboarding requirements. We recommend that the RCE work with the HIN seeking QHIN designation to determine an acceptable deadline.

² 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; RIN 0955-AA01



Health Information Network

We agree there are advantages to allowing flexibility when entities are determining at which level of the TEF they should participate. In particular, because of the broad definition of a HIN, Epic and our customers would have the option to participate at multiple levels of the TEF including the QHIN, Participant, and Participant Member levels.

General Comments (Section 2)

For simplicity and clarity, ONC should split Section 2 into two separate sections—one that describes the application, onboarding, and designation process, and another that describes the operations and obligations of QHINs.

Initial Application, Onboarding, and Designation (Section 2.1)

Requirements for Approval of a QHIN Application (Section 2.1.3)

ONC's intent seems to be that HINs must meet certain "eligibility criteria" in order to apply to be QHINs. If that is the case, ONC should relegate the relevant text (all of the text through the end of subparagraph ii) to its own subsection entitled "HIN Eligibility" before subsection 2.1.1. In addition, ONC should clarify which requirements in the MRTCs are "application prerequisites," or instruct the RCE to determine them.

Subparagraph (i) is duplicative with the earlier definition of a HIN. ONC should remove subparagraph (i) here.

Subparagraph (iii) includes the phrase "in accordance with Applicable Law." ONC should remove this phrase. Any HIN operating today would need to do so in accordance with applicable law. Requiring a HIN and each of its participating entities to prove compliance with applicable law will add unnecessary complexity, time, and cost to the onboarding process.

If ONC wishes to require HINs to be compliant with Section 6 of the MRTCs as a prerequisite to approval of its application to be a QHIN, it should include it as a term in the "eligibility" section described above.

To support these recommendations, ONC should update the draft text as follows:

2.1. Initial Application, Onboarding, and Designation.

2.1.1 Eligibility. A HIN that wishes to become a QHIN must meet the following prerequisites:

- (i) The HIN must already operate in a live clinical environment; and
- (ii) The HIN can provide reasonable evidence that exchange of EHI using its network is occurring in accordance with the requirements of Section 6 below.

2.1.1-2.1.2 QHIN Application. A HIN that wishes to become a QHIN shall begin the process by first delivering to the RCE a completed QHIN Application. The HIN shall promptly make its personnel available to respond to any reasonable questions that the RCE may have about the QHIN Application and promptly provide such further information and documentation that the RCE may reasonably request to process the QHIN Application. If applicable, the HIN shall also make available information relating to personnel of the HIN's vendors and persons or entities that currently use its network in order to address reasonable requests of the RCE.

2.1.2 2.1.3 Timing of Review by RCE. The RCE shall use commercially reasonable efforts to approve or reject each QHIN Application in writing within a stated period after receipt of a completed QHIN Application and all responses to its questions and requests for additional information and documentation, if any, that the RCE has submitted to the HIN. Despite the expiration of the stated period for review by the

RCE, a QHIN Application shall not be deemed approved by the RCE unless and until the RCE issues a written notice of approval to the HIN that submitted it.

~~2.1.3 2.1.4 Requirements for Approval of a QHIN Application. No QHIN Application shall be approved by the RCE unless the HIN certifies in writing and the RCE has confirmed and documented that the HIN in question has satisfied all applicable requirements of the Common Agreement and the QHIN Technical Framework only to the extent they are prerequisites to the RCE signing the Common Agreement with the HIN. At a minimum, such prerequisites shall include the following:~~

- ~~(i) the HIN already operates a network that provides the ability to locate and transmit EHI between multiple persons and/or entities electronically, on demand or pursuant to one or more automated processes;~~
- ~~(ii) such persons and/or entities are already exchanging EHI in a live clinical environment using the network;~~
- ~~(iii) the HIN has provided reasonable evidence that exchange of EHI using its network is occurring in accordance with Applicable Law and the requirements of Section 6 below; and~~
- ~~(iv) the HIN has provided a reasonable plan in writing of how it will achieve within the required period all of the applicable requirements of the Common Agreement and the QHIN Technical Framework that (a) are required for Designation and (b) are required for ongoing operations as a QHIN. The written plan shall include, without limitation, the necessary personnel, technological infrastructure, privacy and security protections, and other appropriate resources, all as described in the ARTCs.~~

Provisional QHIN Status (Section 2.1.4)

ONC should update the proposed text as follows to clarify that “designation as a QHIN” is a reason that a Provisional QHIN’s status may change.

Upon the RCE’s execution of the Common Agreement, the HIN shall automatically become a Provisional QHIN and continue in such status until it either **is Designated as a QHIN**; fails to be Designated by the RCE as a QHIN by the applicable Cohort Deadline; or is terminated by the RCE for material breach of the Common Agreement or failure to be Designated by the RCE.

Requirements for QHIN Designation (Section 2.1.6)

ONC should clarify the onboarding process, and which requirements are prerequisites for QHIN designation. In particular, it is not clear whether a HIN must execute Participant-QHIN agreements with all of its Participants (and corollary Participant Members) prior to receiving QHIN designation. To avoid disrupting interoperability initiatives, ONC should permit participants of existing HINs to continue to exchange EHI according to their current agreements during the onboarding process. This aligns with our recommendations on Section 2.2.8.

Completion of Onboarding Requirements (Section 2.2.8)

The Common Agreement should allow Participants to conduct exchange outside of the TEF regardless of signatory status. It should also be structured to avoid limiting the interoperability of actors. ONC should update the proposed text as follows.

Each QHIN shall ensure that each Participant has completed the necessary Onboarding requirements before the Participant may **exchange EHI with the QHIN** ~~conduct QHIN-facilitated exchange~~.



Termination of Participation in the Common Agreement (Section 2.2.12)

ONC should add a defined voluntary withdrawal mechanism that QHINs, Participants, or Participant Members can use to terminate participation in the Common Agreement.

Completion of Onboarding Requirements: Participants (Section 7.23)

To avoid confusion, ONC should clarify which of the Participant Member obligations described in Section 8 are considered “onboarding requirements.”

Exchange Purposes, Exchange Modalities, and Permitted and Future Uses of EHI

Exchange Purposes and EHI Reciprocity (Sections 2.2.1, 7.1, 8.1)

We agree that all exchanges should be consistent with the defined Exchange Purposes.

USCDI Version Adoption

For the avoidance of doubt, a new version of the USCDI will be the “then applicable” USCDI eighteen months after it is approved by the National Coordinator.

Providers, hospitals, HIT vendors, and other actors will find it burdensome to track separate deadlines for upgrading their HIT for their participation in the TEF versus their participation in Promoting Interoperability/MU. To avoid this, ONC should align USCDI version adoption expectations with other federal regulatory programs that reference ONC certified health IT.

Ongoing Updates to the USCDI

ONC should clarify how it envisions new versions of the USCDI being deemed “current” and implemented in the TEF:

- It is not clear what process the MRTCs refers to with respect to approval. ONC should clarify that the MRTCs are referencing approval via the new Standards Version Advancement Process described in the 21st Century Cures NPRM.
- It is not possible for HIT vendors to know the scope of development necessary to support exchange of additional data classes and elements in a new version of the USCDI before updates are proposed. For this reason, rather than mandating a blanket 18-month deadline, ONC should specify that the RCE will gather stakeholder feedback about the scale of development necessary to adopt the new version of the USCDI and then determine a feasible implementation deadline.
- The MRTCs do not contemplate how a new version of the USCDI would be phased in for live use within the TEF. ONC should specify a rolling adoption with a final deadline rather than a hard cut-over.

Initiating a QHIN Query

We agree with this section.

Responding to a QHIN Query (QHINs)

When a QHIN receives a QHIN Query from another QHIN, the QHIN shall request EHI from appropriate Participants and transmit the response(s) to the QHIN that initiated the QHIN Query.

This text (together with other materials ONC has developed in its work on TEFCA) implies a model where a QHIN operates a single common gateway or hub to facilitate health information exchange. It can also be interpreted to require that a QHIN act as an intermediary by aggregating responses before transmitting them onward. It is not appropriate to imply architectural requirements in the MRTCs, because certain models may not be appropriate in all scenarios. Instead, the MRTCs should define outcomes, and address technical and architectural requirements in the QTF.

ONC should update the proposed text as follows. Please review our detailed comments on the QTF for additional information.

When a QHIN receives a QHIN Query from another QHIN, the QHIN shall facilitate response to that Query by its Participants as appropriate. ~~request EHI from appropriate Participants and transmit the response(s) to the QHIN that initiated the QHIN Query.~~

Requests for EHI (Sections 7.1 and 8.1)

This section begins by stating, “A Participant may request EHI from a QHIN.” This implies that all QHINs possess EHI. Depending on the architecture of the QHIN, this may not be the case. In some models, a QHIN may store or maintain EHI. In others, the QHIN may use a “pass through” model where it facilitates exchange of EHI without storing it. To accommodate each approach, ONC should modify the proposed language as follows:

A Participant may ~~request EHI from a QHIN~~ direct a QHIN to facilitate EHI exchange via a QHIN Query only if all of the following conditions are satisfied:

Allow entities to use preferred exchange models

Requiring QHIN Queries to occur according to the draft MRTCs and QTF may not be optimal for all entities, or across use cases. For example, the broadly successful Carequality network operates a fully federated model where it distributes a “phone book” of connectors to participants. However, this model does not align with TEFCA, and Carequality would not be able to be a QHIN without expending significant resources. Our comments on the QTF provide detailed recommendations to enable flexibility and innovation, while accomplishing the same outcome.

Response to QHIN Queries (Section 7.1)

Paragraph (a) seems to prescribe a model where each Participant acts as a centralized broker or hub that needs to query individual Participant Members for EHI. ONC should modify the proposed text as follows to clarify that the language is not intended to be prescriptive as to the architecture between a Participant and Participant Members:

A Participant shall respond to a request for EHI from a QHIN, pursuant to a QHIN Query, in the following ways:

- (a) When a Participant receives a request for EHI from a QHIN, pursuant to a QHIN Query, the Participant shall **facilitate a response** from appropriate Participant Members and ~~transmit the response(s) it receives from such Participant Members~~ to the ~~QHIN that requested EHI~~ **requestor**.
- (b) If the Participant stores or maintains EHI, the Participant shall also respond by providing all of the EHI it receives in the then applicable USCDI to the extent that all of the following conditions are satisfied:
 - 1. The EHI is appropriate for and relevant to the applicable Exchange Purpose;

2. The EHI is available;
3. The Disclosure of EHI is permitted under and meets all required conditions of Applicable Law; and
4. The Disclosure is in accordance with any applicable Minimum Necessary Requirements as noted in Section 7.19 below.

Notwithstanding the foregoing, a Participant who only provides Individual Access Services shall not be required to respond to requests for EHI except as necessary to respond to an Individual User's request for Individual Access Services, including where such requests utilize a third party.

Permitted and Future Uses of EHI (Sections 2.2.2, 7.2, 8.2)

We agree that QHINs, Participants, and Participant Members in the TEF should be able to exchange, retain, aggregate, Use, and Disclose EHI as outlined in this section.

No EHI Outside the United States (Section 2.2.11)

We appreciate that ONC has included patient-directed international exchange as permissible in TECA. ONC should modify the Common Agreement to allow international provider-to-provider exchange in accordance with applicable law.

We are also concerned that this section will negatively impact HIT vendors' ability to provide technical support to organizations adopting the Common Agreement. For example, it is unclear whether a support representative working abroad would be permitted to log in to a U.S.-based customer's environment to troubleshoot. If a technology vendor or staff member of a healthcare organization is abroad, but able to establish a secure connection with entities participating in the TEF, they should be permitted to do so.

Individual Access Services

Processing of Individual Access Services Request (Sections 2.2.4, 7.14, 8.14)

We agree with the draft process for fulfilling Individual Access Services Requests. ONC should make two clarifications:

- In many sections of the MRTCs the definition of EHI is explicitly limited in scope to the subset of EHI that is in the USCDI. ONC should clarify that the same is true in this section.
- It is unclear whether entities fulfilling Individual Access Services requests are required to fulfill those requests only with respect to the EHI they possess, or whether the entity would be obligated to perform a QHIN Query. ONC should require entities fulfilling Individual Access Services requests to offer the option to initiate a QHIN Query for an Individual asserting his or her rights.

Individual User Access, Use, or Disclosure of EHI (Sections 9.1-9.2)

We agree with these provisions.

Minimum Information and Permitted and Future Uses of EHI

Sections 2.2.2(vi), 7.2(vi), 8.2(vi)

We agree with these provisions.

Meaningful Choice and Written Privacy Summary

Individual Exercise of Meaningful Choice (Sections 2.2.3, 7.3, 8.3)

We agree with the principle that Individuals should be able to exercise a straightforward Meaningful Choice concerning participation in the TEF. ONC should create a robust consent framework for entities to respect the choices of minors, adolescents, and their guardians with respect to consent and Individual Access Services across disparate state requirements. The framework should recognize that in certain scenarios, disclosing entities may be not be permitted to exchange data under applicable law.

Written Privacy Summary (Sections 6.1.5 7.6, 8.6)

We agree with these sections.

Minimum Necessary

Responding Under Conditions of Applicable Law (Sections 2.2.1, 3.3, 7.1, 7.19, 8.1, 8.19)

In order to perform the verification required in this section before transmitting EHI, the responding QHIN, Participant, or Participant Member would need to have thorough knowledge of Applicable Law of both their own jurisdiction, and of the requestor's jurisdiction. At the time of a query, it will be infeasible for a responding QHIN, Participant, or Participant Member to programmatically verify that a request for the EHI is in accordance with Applicable Law in both jurisdictions.

A requestor would be best positioned to ensure that EHI requested is permitted to be disclosed in their local jurisdiction. Placing this expectation on requestors reduces burden and streamlines exchange by only requiring knowledge of Applicable Law relevant to one's own jurisdiction.

Appropriateness of EHI

A requestor would be best positioned to determine what EHI is appropriate for a given Exchange Purpose, and should be expected to only request appropriate EHI. A respondent to a request for EHI would have limited ability to determine whether any given element of EHI is appropriate for transmission to the requestor.

Responding/Disclosing in Accordance with Minimum Necessary Requirements

Responding systems of QHINs, Participants, and Participant Members would not have a programmatic mechanism to assess whether the EHI requested is in accordance with applicable Minimum Necessary requirements. As a result, manual intervention would be needed in many cases, (i.e. any use case that is not Treatment, Payment, or Health Care Operations) to determine whether a particular request for EHI was in accordance with those requirements.

The receiving system would be best positioned to determine whether a request for EHI meets Minimum Necessary and other requirements according to applicable law. The entity that is querying a QHIN, Participant, or Participant Member should conduct a Minimum Necessary analysis as a prerequisite to requesting EHI via the TEF, and only request EHI that the analysis has deemed appropriate. Any entity responding to a query should be able to reasonably assume that the EHI requested satisfies Minimum Necessary requirements.

Mandatory Updating of Technical Capacity, Connectivity Services, and Agreements

Mandatory Updating of Technical Capacity (Section 2.2.5)

Please see our earlier feedback in the Exchange Purposes and EHI Reciprocity section on timelines for adopting initial and ongoing USCDI updates.

Mandatory Updating of Participant-QHIN Agreements (Section 7.22)

This section references the “then applicable USCDI” when it obligates Participants to exchange EHI. Because the standard is referenced in a version agnostic manner, it is unclear why updates to Participant-QHIN Agreements would be necessary in the event that a new version of the USCDI is adopted as current. ONC should remove this requirement.

Failure to Incorporate Mandatory Minimum Obligations in Participant-QHIN Agreement (Section 2.2.7)

This section is duplicative with the text in Section 7. ONC should remove this section to avoid confusion.

Compliance with the QHIN Technical Framework (Section 2.2.9)

Timeline for Implementation

The scale of changes included within an update to the QTF could vary widely. Many will be achievable in 18 months but there will also be changes that take longer to implement. Instead of mandating a blanket 18-month period for all updates, ONC should specify that the RCE gather stakeholder feedback about the scale of development necessary to adopt the new version of the USCDI and mutually agree with stakeholders on an implementation deadline. This feedback could be solicited in conjunction with the RCE soliciting feedback on the actual updates to the QTF.

Compliance with Minimum Obligations (Section 7.24)

Annual collection of compliance confirmations will be burdensome and time-consuming for Participants with numerous Participant Members. ONC should remove this requirement.

Data Quality

Patient Demographic Data for Matching (Section 3.1)

The QHIN Technical Framework does not label any set of data as “Patient Matching Data.” To avoid confusion, ONC should clarify that this section refers to the elements included in the Patient Demographics data class of the USCDI.

Data Quality Characteristics (Section 3.2)

This expectation may be reasonable for the operating models of some QHINs. However, this type of assessment will be extraneous for QHINS that do not maintain a centralized Master Patient Index or other similar service. ONC should define the scenarios and/or models in which this requirement is applicable.

The MRTCs do not specify a target score that QHINs are expected to accomplish on the assessment. We agree that this is appropriate, and recommend that entities complete the assessment as an informational tool to identify potential areas for improvement.

Non-Discrimination

Prohibition Against Exclusivity (Section 5.1.1)

We believe that this principle is critical to the success of any Trusted Exchange Framework. ONC should broaden the requirement beyond other QHINs to include Participants and Participant Members:

A QHIN may not require exclusivity or otherwise prohibit (or attempt to prohibit) any of its Participants from joining, exchanging EHI with, conducting other transactions with, using the services of, or supporting any other QHIN, **Participant, or Participant Member.**

No Discriminatory Limits on Exchange of EHI (Sections 5.1.2, 7.5, 8.5)

A QHIN shall not unfairly or unreasonably limit exchange or interoperability with any other QHIN, Participant, Participant Member, or Individual User such as by means of burdensome testing requirements that are applied in a discriminatory manner or other means that limit the ability of a QHIN to send or receive EHI with another QHIN, Participant, Participant Member, or Individual User or slows down the rate at which such EHI is sent or received if such limitation or slower rate would have an anti-competitive effect.

As used in this Section 5, a discriminatory manner means action that is taken or not taken with respect to any QHIN, Participant, Participant Member, Individual User, or group of them due to the role it plays in the health care system, whether it is a competitor, whether it is affiliated with or has a contractual relationship with any other entity, or whether it has or fails to have any other characteristic; provided, however, that limitations, load balancing of network traffic or other activities, protocols or rules shall not be deemed discriminatory to the extent that they either:

- (i) benefit patients by prioritizing Treatment over other activities; or
- (ii) are based on a reasonable and good faith belief that the other entity or group has not satisfied or will not be able to satisfy the applicable terms hereof (including compliance with Applicable Law) in any material respect including, if applicable, Section 7 or Section 8 below.

For example, imposing different testing requirements on a QHIN because it primarily serves providers that are not users of a certain electronic health record system or because it primarily serves payers would be considered discriminatory for purposes of this Section.

Inclusion of the term “interoperability”

In this section, the MRTCs state, “A QHIN shall not unfairly or unreasonably limit exchange **or interoperability.**” However, the term “interoperability” is not defined for use in this section. ONC should remove this term from the MRTCs.

Any actor participating in the TEF subject to the Information Blocking (and corollary interoperability) provisions set forth in 45 CFR Part 171 or other applicable law would need to continue to abide by those expectations. However, adjudication and enforcement of that expectation should not be inadvertently included in the scope of the Common Agreement of the TEF.

Definition of Discrimination

Discrimination (and its correlative term “Discriminatory Manner”) should be defined in Section 1 of the MRTCs for consistency. To avoid frivolous disputes, ONC should update the definition of Discriminatory Manner to make clear that an actor accused of discriminatory behavior must have done so deliberately:

...[A] discriminatory manner means action that is **deliberately** taken or not taken with respect to any QHIN, Participant, Participant Member, Individual User, or group of them due to the role it plays in the health care system, whether it is a competitor, whether it is affiliated with or has a contractual relationship with any other entity, or whether it has or fails to have any other characteristic; ...

Adjudication of accusations of discrimination

ONC should clarify that the RCE would be responsible for adjudicating claims of discrimination. The RCE should use objective criteria to determine whether a QHIN is engaging in discriminatory behavior. In particular, it will be important to define objective tests for:

- The point at which throttling or other actions that purport to “prioritize Treatment over other activities” may implicate the definition of discrimination
- Determining that an entity has not satisfied the applicable terms or the Common Agreement

In any case, a thorough and speedy fact-based investigation and adjudication framework should be used.

Limitation to Section 8

For the purposes of the definition of discrimination, the obligations that must be satisfied by QHINs, Participants, and Participant Members are constricted to those defined to those in Section 8. We believe that it would be more appropriate to refer to satisfaction of “relevant obligations” of the Common Agreement:

are based on a reasonable and good faith belief that the other entity or group has not satisfied or will not be able to satisfy the **minimum relevant** obligations stated in Section 8 of the Common Agreement (including compliance with Applicable Law) in any material respect.

Fees

Access to Participant-QHIN Agreements including Fees (Section 4.1.1)

We agree that transparency in agreements between the Participant and a QHIN, as they relate to participating in QHIN facilitated exchange, is important. ONC should clarify that this transparency is specific in scope to the agreement between a Participant and QHIN that details legal rights and obligations with respect to exchange in the TEF, analogous to Carequality Connection Terms or other similar arrangements.

Fee Schedule (Section 4.1.2)

We agree that transparency in a QHIN’s fee schedule with respect to services provided in the TEF is important. ONC should clarify that this requirement applies to transaction fees that a QHIN charges in relation to services provided in the TEF, and not to other product lines that an entity operating a QHIN might offer.

Fees (Section 5.2)

We agree with this section.

Breach Notification

Sections 6.1.1-6.1.2

ONC should clarify that these requirements apply to the extent that a QHIN stores, maintains, or aggregates EHI on its own behalf and are not intended to supplant rights or obligations that a Participant or Participant Member might have under HIPAA or other applicable law.

Sections 7.12-7.13 and 8.12-8.13

We agree with these sections.

Other Legal Requirements

Other Legal Requirements (Sections 6.1.4, 7.4, 8.4)

We agree with this section. It may be advantageous to clarify that the MRTCs themselves do not place any additional burden on actors to obtain an Individual's consent.

Demand for Compulsory Disclosures (Section 6.1.3)

ONC should clarify that these requirements apply to the extent that a QHIN stores, maintains, or aggregates EHI on its own behalf and are not intended to supplant rights or obligations that a Participant or Participant Member might have under HIPAA or other applicable law.

ONC should clarify that if an entity does not possess the EHI that is the subject of the demand for compulsory disclosure, it is not obligated to act as the mechanism for a compulsory disclosure to be satisfied.

Minimum EHI Security Requirements

Minimum EHI Security Requirements (Sections 6.2, 7.7, and 8.7)

To avoid ambiguity and stakeholder confusion, ONC should reference the sections of the HIPAA Rules that entities are expected to comply with directly rather than using a partial list in the MRTCs.

ONC should clarify that these requirements apply to the extent that a QHIN stores, maintains, or aggregates EHI on its own behalf and are not intended to supplant rights or obligations that a Participant or Participant Member might have under HIPAA or other applicable law. If that is not the case, the MRTCs should clarify the full extent of QHIN obligations on behalf of its Participants and Participant Members.

Application of NIST Standards and ONC/OCR Security Risk Assessment Tool (Section 6.2.1)

We agree with this section

Data Integrity

Sections 6.2.2, 7.16, 8.16

We agree with these sections.

Authorization

Sections 6.2.3, 7.8, 8.8

We agree with these sections.

Identity Proofing

Sections 6.2.4, 7.9, 8.9

We agree with these sections.

Section 9.3

We agree with these sections. We note that there may be certain patient populations for whom meeting this expectation will be challenging, such as indigent patients. The RCE should convene a multi-stakeholder task force to address this challenge. The task force could examine analogous approaches taken by groups working with homeless veterans, for example.

User Authentication

Sections 6.2.5, 7.10, 8.10, 9.4

ONC should clarify that these sections do not preclude system-automated health information exchange. In certain scenarios, it may improve usability and efficiency for health IT systems to perform automated queries (e.g., automatically retrieving information overnight for appointments scheduled the next day).

ONC should revise the MRTCs to specify that automated exchange between two IT systems using modern encryption and security technology does not require two-factor authentication, because there is no person involved in the exchange.

Summary of Disclosures of EHI

Sections 6.1.6, 7.20, 8.20

ONC should clarify that this section applies to the extent that a QHIN, Participant, or Participant Member stores, maintains, or aggregates EHI on its own behalf and possesses the relevant audit trails. If the entity does not possess or maintain such information, it should instead be sought from the relevant Participants or Participant Members.

Section 9.5

We agree with this section.

Transport Security

Sections 6.2.6, 7.17, 8.17

We agree with these sections.

Auditable Events

Sections 6.2.8, 7.11, 8.11

We agree with these sections.



Qualified Health Information Network Technical Framework

Functions and Technology to Support Exchange

Certificate Policy

We agree that it is appropriate for the RCE to be responsible for management and administration of Certificate Authorities, and that it is appropriate for QHINs to possess digital certificates for authentication, encryption, and signing.

Secure Channel

We agree that TLS is an appropriate protocol to secure transactions that take place in the QHIN Exchange Network.

ONC requests comment on whether the QTF should specify additional standards or approaches for securing QHIN Exchange Network transactions. Starting with a single, baseline approach would be best for facilitating a rapid “ramp-up” to exchange. Holding all QHINs to a single set of expectations for establishing a secure channel will be helpful for QHINs’ understanding of the requirements, and will facilitate building trust amongst entities connected in the QHIN Exchange Network. Further, since TLS is broadly adopted already, it will be more straightforward for QHINs to meet this expectation. Introducing additional allowable standards in the future may be appropriate if the consensus across the industry is that they are mature enough for use in the QTF.

Mutual QHIN Server Authentication

We agree with this expectation.

User Authentication

We agree with this expectation.

Authorization and Exchange Purpose

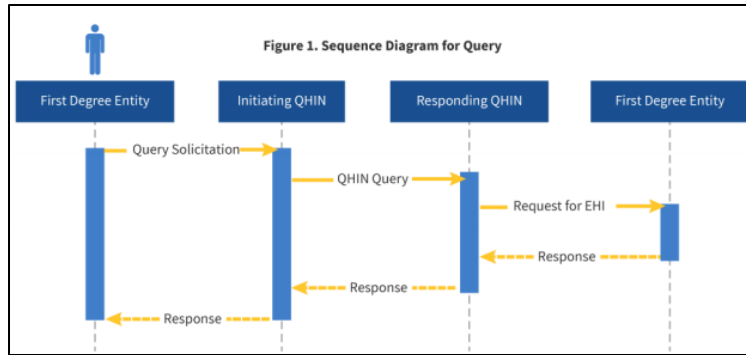
We agree with this expectation.

Query

We agree that the IHE XCA and XCPD standards are appropriate for implementation of the QHIN Query function that the TEF envisions. However, we believe that that these functions should be implemented differently than is described in the Introduction, MRTCs, and QTF. In particular, implementing document exchange via the QHIN Query flow will introduce artificial and unnecessary bottlenecks that will severely harm the sustainability and usability of the QHIN Exchange Network.

Sequence Diagram for Query

The QTF includes the following sequence diagram for conducting a QHIN Query. We believe that this diagram is too high level for entities and may inadvertently lead to inefficient implementation of the standards. ONC should instead reference schematics in the IHE implementation guide directly to provide greater clarity.



We are also concerned that the diagram implies an exchange model that requires QHINs to operate centralized brokers. Requiring QHINs to use centralized models would force most U.S. healthcare providers to choose between remaining outside the trusted exchange framework or being harmed by high interoperability costs passed down by the QHINs. This is because centralized models have high initial and ongoing costs including data center and infrastructure setup, staffing, security and storage. OHINs would pass these costs to their members.

Most U.S. Healthcare organizations today connect through HINs that use federated or other non-centralized models. These models are simpler to set up and maintain than centralized models and almost always cost participants less.

ONC should adopt a model-agnostic approach so that the HINs serving the majority of U.S. healthcare providers today can become QHINs. This would allow HINs that have centralized models to keep them, and also allow healthcare providers that are not yet connected through HINs to choose the model they prefer. We provide detailed input below on establishing a model-agnostic approach.

Query Solicitation

ONC should clarify that the following elements are intended to be included as part of the Query Solicitation:

- User Authentication between the First Degree Entity and Initiating QHIN
- Authorization and Exchange Purpose functions
- Transmission of patient demographic information for use in XCPD requests
- Transmission of query parameters to include in XCA requests
- Retrieval of located documents

The QTF seems to envision that all of these elements would be included in a single transaction. However, that expectation would be contrary to modern networking norms to the detriment of the efficiency of the QHIN Exchange Network. ONC should revise the QTF to clarify that these steps can take place over a number of incremental transactions rather than in a single transaction.

QHIN Query

The diagram above seems to envision that QHINs would complete both the patient identity resolution workflow and document retrieval workflow in a single step. It further seems to envision that all located and retrieved documents would be returned to the requestor in a single transaction.

In the case of a QHIN Broadcast Query, all responding QHINs would conduct all of those steps before returning any response to the initiating QHIN. The initiating QHIN would then wait until all QHINs have responded before returning any EHI to the Participant requestor.

We believe that requiring QHIN Queries to occur according to the diagram above will create artificial bottlenecks that impede the performance of the QHIN Exchange Network. In particular, requiring the aggregation of results from each QHIN for response in a single transaction forces queries to move at the pace of the slowest respondent at each step (i.e., 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).

Additionally, requiring that all documents be returned in full will inflate the size of the response message with potentially duplicative and unnecessary information. This will further extend the amount of time it takes for responses to be returned to the requesting Participant, be unsustainably taxing on the network's bandwidth, and increase the risk to patient privacy.

To address these issues, ONC should modify the QTF to incorporate the feedback below.

[Allow incremental completion of steps](#)

Requiring multiple steps of the query process to be conducted in a single transaction is inefficient and harms the usability of the network. Instead, the QTF should reference the IHE Implementation Guides, which implements each stage of a QHIN Query, including patient identity resolution, document location, and document retrieval, as a series of transactions.

[Allow granular steps for patient identity resolution and record location](#)

The QTF should be revised to directly refer to the IHE implementation guides and permit these steps to be executed as a series of transactions during the execution of a QHIN Query.

The QTF should specifically permit flexibility in how a QHIN handles Patient Identity Resolution. Some QHINs may choose to maintain a centralized master patient index on behalf of their Participants, while others may choose to implement a federated approach where they propagate XCPD requests to their Participants and rely on the Participants to resolve patient identity. The benefits and tradeoffs may vary across use cases and across classes of QHINs (e.g., QHINs that primarily serve large integrated delivery networks may find approach X superior while QHINs that serve small clinics may find approach Y superior). The QTF should remain flexible to allow new, innovative approaches. The IHE implementation guides for query workflows are intentionally approach-agnostic for this reason.

The QTF should take a similar approach with respect to record location. So long as the obligation to respond to queries is maintained and QHINs are able to facilitate responses to the requestor, a specific approach should not be prescribed.

[Return a list of documents before retrieval](#)

When a query is executed for patient health information, a significant number of the documents returned may duplicate information returned from a previous query. If a requestor has the opportunity to identify those duplicative documents (e.g., by comparing the metadata with metadata for previously retrieved documents) it might determine that it is not necessary to retrieve the full document from the respondent. The QTF should reference the IHE implementation guide and include this step in the query

workflow. Doing so would reduce the server capacity, storage, and bandwidth needed to execute queries and improve the performance and sustainability of the network.

[Do not require QHIN-level aggregation of responses in any step](#)

The documentation that ONC has released describing TEFCA seems to envision that in a query workflow, responding QHINs would aggregate responses from participants in both the patient matching and document exchange steps before responding to the requestor. 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 forces 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. In the case of a query for treatment purposes (especially in emergency situations), this delay in access to information would introduce patient safety risks.

Responses to queries should be permitted to be transmitted back to the requestor as they occur in real time. That way, QHINs would have the flexibility to aggregate responses from its Participants if it is optimal in its operating model, or facilitate transmission of responses as they occur. This flexibility will result in greater usability of the network, and should be defined in a standard to facilitate proper implementation across the industry.

[Allow flexibility in which entity responds to the requestor](#)

To further promote efficiency in the QHIN Exchange Network, the QTF should not be prescriptive in which entity ultimately responds to the requestor. Rather, the QTF should require that QHINs are merely 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 to manage a connection with. Others might adopt a federated approach where the QHIN propagates the query to its Participants, who are then responsible for returning a response to the requestor directly. In this scenario, the QHIN would merely ensure that all Participants received the request, and include information on to whom respondents should return a response.

Both of these approaches have been implemented in practice and have been successful. Existing federated networks have demonstrated that these approaches can coexist and seamlessly exchange data within a single network.

[Cost and Performance of a Broadcast Query](#)

We agree that the capability to conduct an all-encompassing Broadcast Query 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 broadcast queries in a manner that is cost efficient and does not result in prohibitive "loading times."

In the U.S., there are in excess of 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 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. We anticipate that the volume of those requests would be similarly substantial.

The sheer volume of 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. ONC should reconsider its inclusion of broadcast query functionality in the TEF until the industry is better prepared to support it. Absent that revision, clear guidance will be needed to delineate when it is appropriate to execute a broadcast query in order to preserve the sustainability of the network.

As an alternative to requiring broadcast queries at the initial launch of the QHIN Exchange Network, the TEF should include the capability of conducting “smart queries” as a functionality. 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 they seek. For example, a smart query could specifically target organizations based on a patients’ home and work addresses.

ONC should include smart queries as an incremental step towards a true broadcast query until mature standards to conduct broadcast queries allow for efficient scalability.

[ONC Request for Comment #4](#)

We are in favor of a generally non-prescriptive approach and allowing for variation of implementations. As ONC has identified, Carequality has successfully implemented and scaled a network that allows variance in how the standards are implemented, so long as they follow a nominal flow. The success of the Carequality network demonstrates that varied approaches can still seamlessly exchange data. ONC should adopt a similar approach here to leverage the massive investments already made in exchange infrastructure.

[ONC Request for Comment #5](#)

We believe QHINs may find it advantageous to implement the broad array of query types included in the IHE XCA profile. For consistency, ONC should modify the QTF to specify which queries and parameters entities must support for specific use cases and exchange purposes.

[ONC Request for Comment #6](#)

We agree that document-based exchange is not necessarily conducive to more granular data needs, and that the HL7 FHIR standard would be most appropriate to meet granular data needs.

[Message Delivery](#)

We agree that XCDR is an appropriate standard for use for QHIN Message Delivery. Because XCDR requires an authoritative provider directory, the TEF should implement a nationwide directory of exchange ready Participants and Participant Members.

We believe the QTF should allow flexibility in how this function is executed to avoid inadvertently introducing bottlenecks in the QHIN Exchange Network. In the case of QHIN Message Delivery, this flexibility should be introduced by explicitly *not* requiring that requestors route pushed EHI through QHINs. Rather, entities should have the flexibility to directly push EHI to the intended recipient if it possesses sufficient directory information to do so. Similarly, the recipient should have the flexibility to deliver acknowledgement messages directly to the entity that initially sent the EHI.



Patient Identity Resolution

We understand this to mean that to the extent that a QHIN maintains patient identity information on its own behalf, it must be able to resolve requests to match patient demographic information. If, however, a QHIN does not maintain a centralized master patient index and relies on a federated approach, the QHIN could operate more of a “pass through” model whereby it facilitates propagation of requests to its Participants who then resolve patient identity matching requests. If this interpretation is correct, we agree that this is an appropriate level of flexibility for QHINs. If not, the QTF should be revised to allow this flexibility.

ONC Request for Comment #7

We believe that the data elements included in the patient demographics class of the USCDI would add value to patient demographics matching requests. To our knowledge, they can all be used in XCPD transactions.

In particular, requiring inclusion of USPS formatted addresses, telephone numbers, and email addresses in patient matching transactions could improve patient match rates. This data is either already commonly collected, or could easily be collected with low effort. Inclusion in XCPD transactions on a consistent basis would result in significant improvements in patient match rates.

ONC should work with the USPS to create and deploy an API that can be used at no or low cost by healthcare organizations to standardize patient addresses into USPS format as well as verify an address is deliverable.

ONC Request for Comment #8

We agree that the QTF should adopt a non-prescriptive approach for patient matching so that QHINs and other actors engaging in EHI Exchange via the QHIN Exchange Network are able to adopt the option that is optimal for their individual business needs and allows for innovation.

We disagree with the assertion that “Federated approaches may... be harder to scale across many communities.” Epic has found that a federated approach is cost-effective and scalable while maintaining patient matching functionality that is at least as robust as that of centralized models. Organizations utilizing our Care Everywhere software to exchange EHI leverage a federated model to exchange in excess of 4 million patient records each day, and over 5 billion records since its first live use. About 40% of daily exchange volume takes place with organizations using other vendors’ products as well as HINs, industry networks such as Carequality, and government agencies such as the Social Security Administration.

The success of the Carequality network has demonstrated that HINs leveraging federated and centralized patient matching can coexist in a single “network of networks” and seamlessly exchange health information across communities leveraging differing approaches.

ONC Request for Comment #9

Currently, there is no industry consensus on a single way to measure and compare performance on patient matching success rates, so it is unclear how minimum performance standard would be implemented. If ONC and other policymakers determine that it is appropriate to establish a performance standard, a number of steps would be needed including:

- Establishment of a test patient data set with known duplicate rates to measure performance against

- Determination of appropriate metrics that have validity across solutions and that are acceptable across use cases
- Establishment of a consensus based testing methodology administered under the oversight of a neutral party

ONC should not include a specific performance target until this testing framework exists. It may be appropriate for ONC to work with the RCE to study the matter further to determine what practical measurement can be conducted prior to determining whether a performance target should be established.

Record Location

We agree that granting QHINs flexibility to determine the optimal approach for their own participants will result in more efficient and sustainable exchange. To better reflect this flexibility, ONC should revise the proposed language as follows:

A QHIN MUST be capable of facilitating accurate identification of the location of all appropriate patient EHI prior to responding to a QHIN Query
--

ONC recognizes the criticality of “accurate” record location to the success of any exchange network. However, the term “accurate” is not defined. If there is a certain level of accuracy are entities expected to attain with respect to record location, ONC should specify it.

ONC Request for Comment #10

We do not believe that the QTF should specify a single standardized approach across QHINs. The success of the Carequality network has demonstrated that HINs leveraging federated and centralized approaches can coexist in a single “network of networks” and seamlessly exchange health information across communities leveraging differing approaches.

Directory Services

ONC Request for Comment #11

Directory Services must be implemented in order for the XCDR standard to be used effectively. Therefore, we believe it is appropriate for the QTF to incorporate Directory Services. We believe the approach the Argonaut Project has taken would best meet the needs described.

Directory Services is an area where implementing a single, standardized, centralized approach is distinctly superior to entities maintaining separate directories. This approach is superior because it is more straightforward to have a single authoritative “source of truth” for where EHI should be transmitted. In order to be successful with this approach, ONC should work with its partners at CMS and the selected RCE to determine maintenance and governance over a single national provider directory. This could be an adapted version of NPPES, or it could start from scratch. However, it is essential that a single provider directory is considered authoritative.

If ONC takes the approach of leveraging work already completed in implementing the NPPES, some modifications will be necessary. In particular, Direct Addresses *must* be captured on a consistent basis, and associated with a specific physical address for a provider. Further, there would need to be a clear obligation on the part of all entities participating in TEF to maintain accurate and up-to-date entries in the directory. This expectation could be set in the MRTCs at the QHIN level. We expect that in practice, QHINs

would then propagate this expectation down to its Participants (and Participants to its Participant Members) via a section in the QHIN-Participant Agreement.

Individual Privacy Preferences

- A QHIN MUST collect and utilize Meaningful Choice notices received from any First Degree Entity or QHIN
 - A QHIN MUST electronically communicate Meaningful Choice notices to all other QHINs
 - A QHIN MUST electronically maintain Meaningful Choice notices
 - A QHIN MUST use electronically maintained Meaningful Choice notices to determine whether to initiate QHIN Queries or QHIN Message Deliveries

This text assumes all QHINs would maintain a centralized consent registry on behalf of their Participants. Consistent with our feedback elsewhere on the MRTCs and the QTF, we believe this approach is overly prescriptive. ONC should update the proposed language to give QHINs flexibility to optimize their approach to Meaningful Choice notices based on their Participants' needs.

ONC Request for Comment #12

ONC should examine the work that industry groups like Carequality have completed on policy and technical standards for consent, authorization, and Meaningful Choice. Consistently capturing, interpreting, and propagating Meaningful Choice decisions merits further study and maturation prior to prescription of a specific format. The RCE should convene stakeholders including patient advocates, technology vendors, and healthcare organizations to continue driving progress in this area.

ONC Request for Comment #13

We recommend the RCE convene stakeholders in a task force to determine whether existing standards meet the needs of the TEF prior to specifying a standard in the QTF.

Auditing

We agree that these requirements are appropriate for QHINs to adhere to for auditing purposes. If the recommendations for allowing flexibility in the operating model of QHINs are incorporated into the final version of the Common Agreement and QTF, QHINs will differ in the metadata collected for auditing purposes. The MRTCs will need to allow for this variation.

ONC Request for Comment #14

The activities ONC has identified seem appropriate to the extent that a QHIN conducts them on its own behalf. We anticipate that metadata captured and exchanged via the standards included in the QTF will provide sufficient event information.

Error Handling

We agree that it is appropriate to expect QHINs to facilitate handling of error messages.

ONC Request for Comment #15

We agree it is appropriate for the QTF to specify a consistent set of error messages for interactions between QHINs and other entities exchanging EHI via the QHIN Exchange Network. The RCE will be best suited to gather stakeholder input on which error messages and associated standards for implementation will best meet the needs of entities participating in the QHIN Exchange Network.