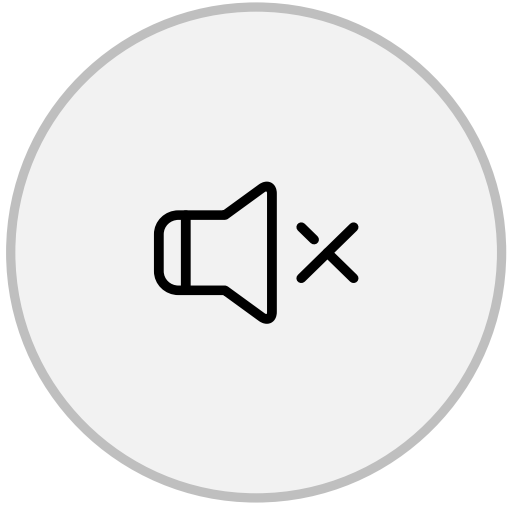
AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Town Hall: IIS Comments on TEFCA Draft 2

May 23, 2019
3pm – 4pm ET

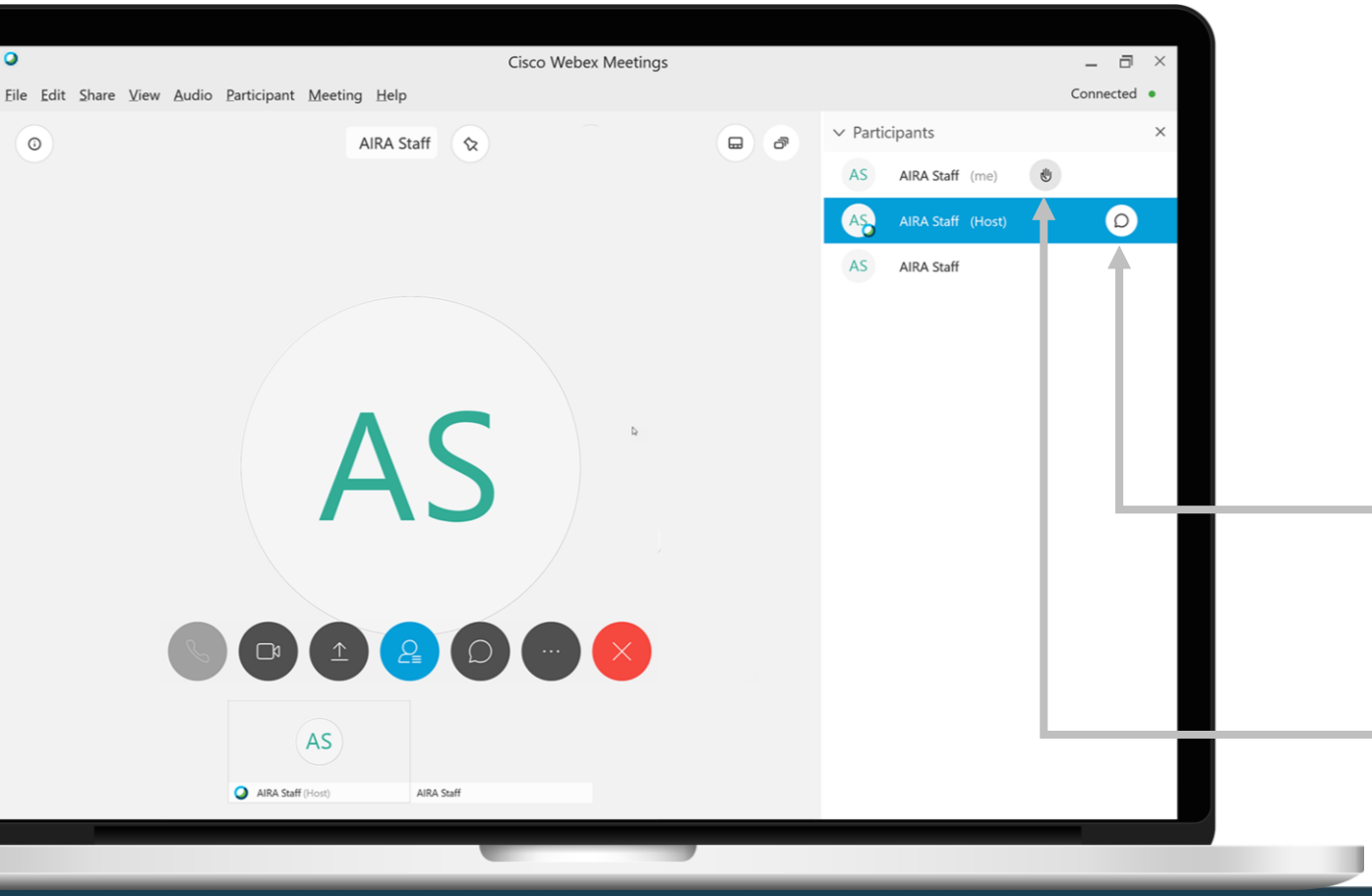
Welcome



All phone lines
are muted

This meeting is being recorded
and will be posted on the
AIRA repository

Welcome



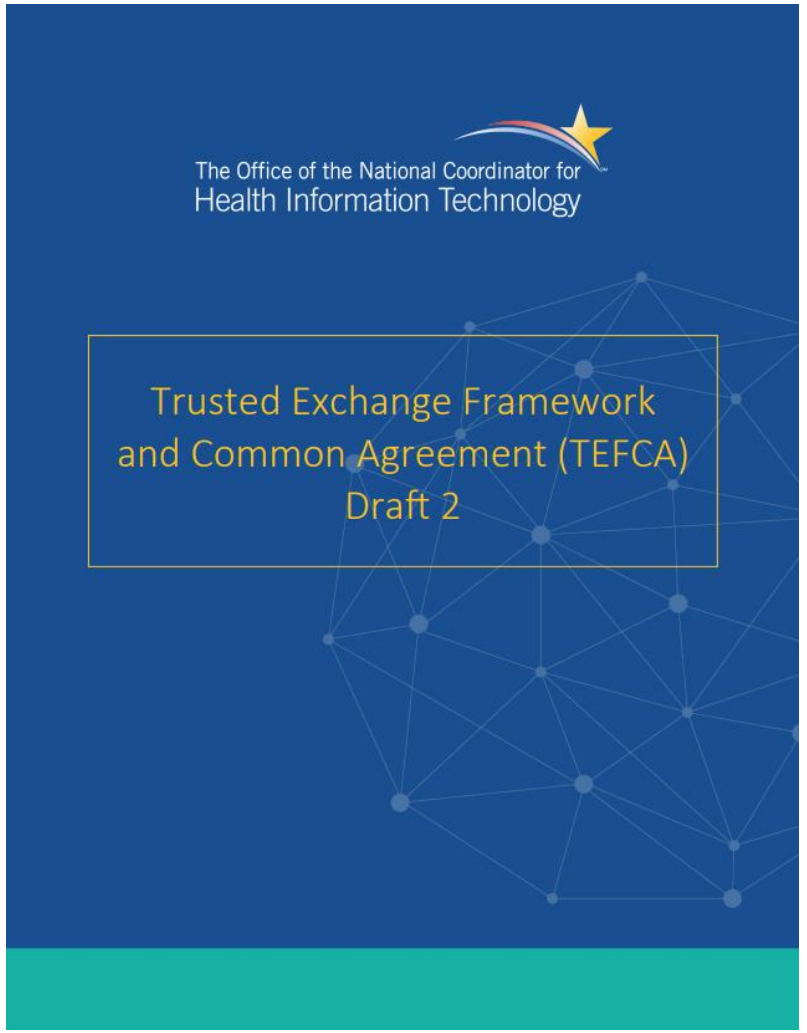
- **How do I ask a question?**
  - There will be time allotted for Q&A following the presentation, to unmute your line press *6
  - Via WebEx:

Select the chat icon next to the host and type question into the chat box.

Select the hand icon next to your name and you will be called on.

Overview for this Session

- Provide overview of TEFCA Materials
- Review/affirm submitted comments
- Discuss additional comments
- Confirm next steps



Schedule for Compiling AIRA Comments

- **May 23, 3pm ET**: Town Hall to review submitted comments
- **Week of May 28**: Compiled DRAFT comments shared with IIS community
- **June 3**: Edits on DRAFT comments due back to AIRA
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- **June 17**: Comments submitted to ONC by deadline*

**Ideally by AIRA and by member jurisdictions*

All materials can be found at: https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

Compilation of Comments

- Thank you to all the AIRA members, the Task Force for Promoting Interoperability, community partners (ASTHO, CSTE, etc.), and others who discussed, considered, brainstormed, and contributed to these comments
- Thanks to ONC, who provided great materials and graphics
- We'll review:
  - Comments of Support
  - Comments of Concern
  - Comments for Discussion

Key Acronyms

- **TEFCA** – Trusted Exchange Framework and Common Agreement
- **MRTCs** – Minimum Required Terms and Conditions
- **ARTCs** – Additional Required Terms and Conditions
- **QHIN** – Qualified Health Information Network
- **QTF** – QHIN Technical Framework
- **RCE** – Recognized Coordinating Entity
- **NPRM** – Notice of Proposed Rule Making

Note: there is a full definitions section that includes all acronyms on pages 32-39 of the TEFCA document

What Brought Us Here?

- The **21st Century Cures Act** , **passed** overwhelmingly in both the U.S. House of Representatives and Senate with strong bipartisan support, and was signed into **law** on December 13, 2016.
- In section 4003 of the Cures Act, Congress directed ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks (HINs) nationally."

What Brought Us Here?

- ONC has focused on three high-level goals within TEFCA:

Provide a single “on-ramp” to nationwide connectivity

Enable Electronic Health Information (EHI) to securely follow the patient when and where it is needed

Support nationwide scalability

What is the Trusted Exchange Framework?

The TEF is a set of common principles that are designed to facilitate trust among Health Information Networks (HINs) – rules of the road

Principle 1 – Standardization	• Adhere to industry and federally recognized standards, policies, best practices, and procedures.
Principle 2 – Transparency	• Conduct all exchange and operations openly and transparently.
Principle 3 – Cooperation and Non-Discrimination	• Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.
Principle 4 – Privacy, Security, and Safety	• Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.
Principle 5 – Access	• Ensure that individuals and their authorized caregivers have easy access to their EHI.
Principle 6 – Population-Level Data	• Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

What is the Common Agreement?

The Common Agreement provides the governance necessary to scale a functioning system of connected HINs that will grow over time to meet the demands of patients, clinicians, and payers

Minimum Required Terms & Conditions (MRTCs)

- ONC will develop mandatory minimum required terms and conditions that Qualified Health Information Networks (QHINs) who agree to the Common Agreement would abide by.

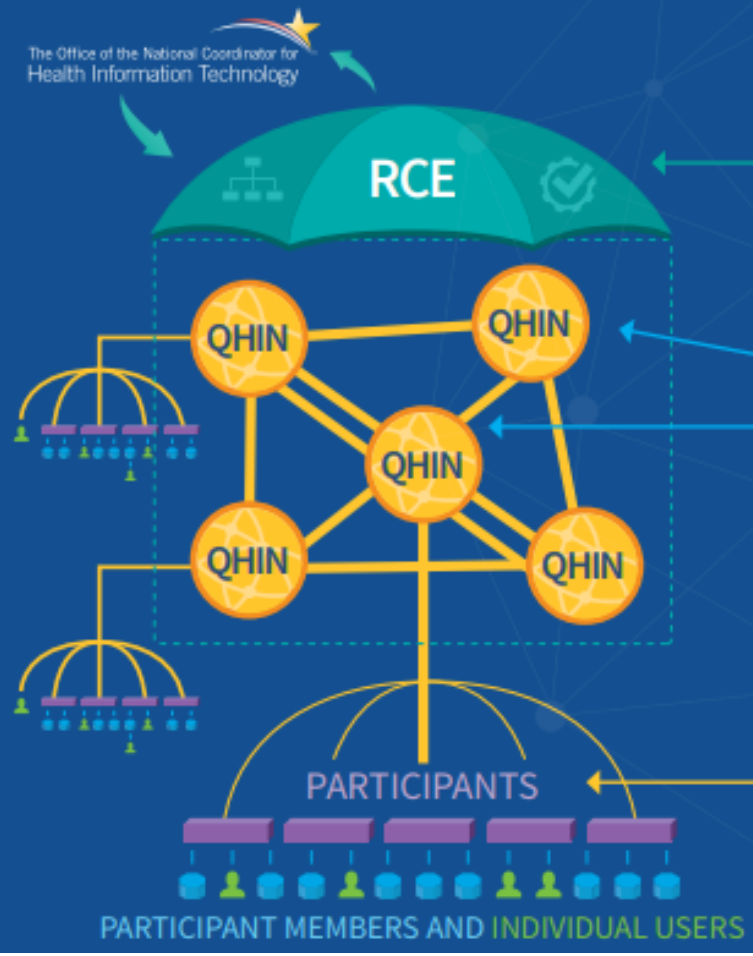
Additional Required Terms & Conditions (ARTCs)

- In addition to the MRTCs, the Common Agreement will include additional required terms and conditions that are necessary for the day-today operation of an effective data sharing agreement. The Recognized Coordinating Entity (RCE) will develop the ARTCs and ONC will have final approval.

QHIN Technical Framework (QTF) – *incorporated by reference*

- Signatories to the Common Agreement must abide by the QHIN Technical Framework, which specifies functional and technical requirements for exchange among QHINS. The RCE will work with ONC and stakeholders to modify and update the QTF.

How Will the Common Agreement Work?



RCE provides oversight and governance for QHINs.

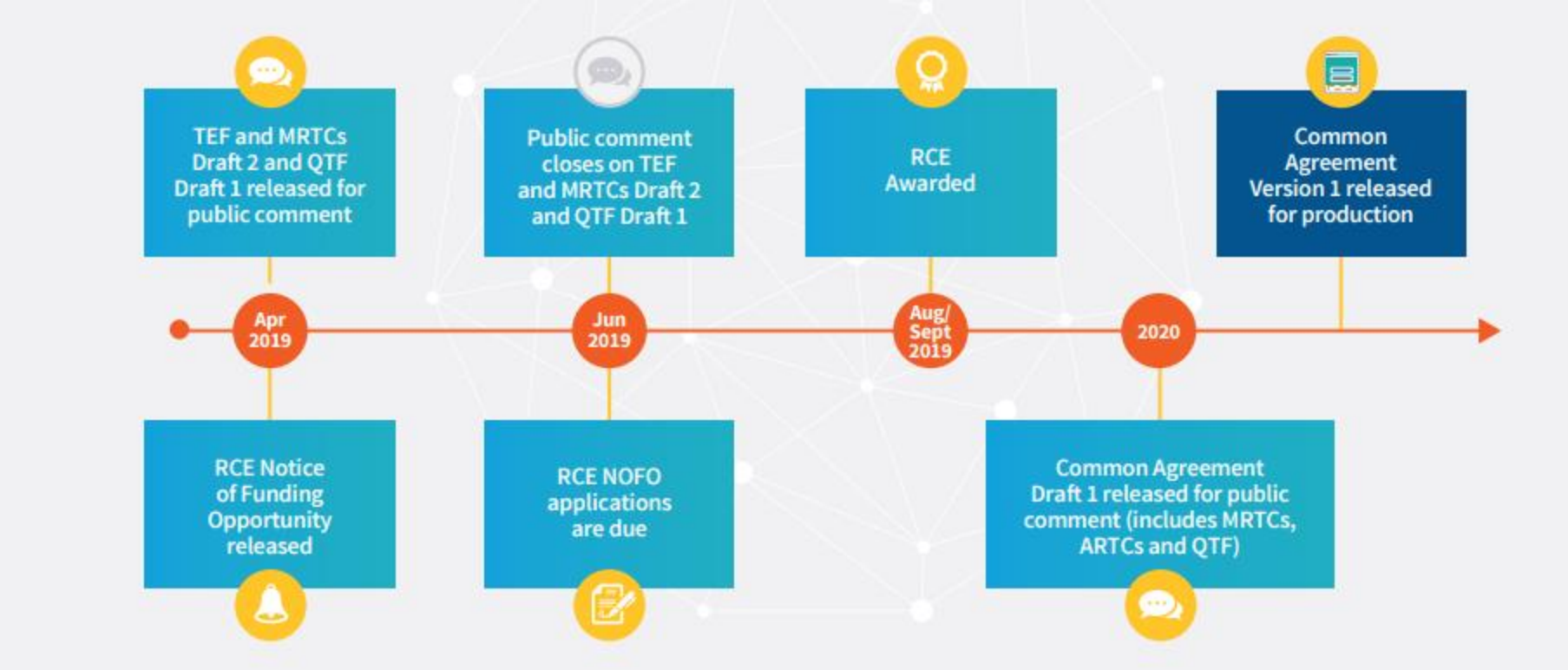
QHINs connect directly to each other to facilitate nationwide interoperability.

Each QHIN represents a variety of Participants that they connect together, serving a wide range of Participant Members and Individual Users.

ONC TEFCA User's Guide: https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf, accessed 5/22/2019

High-Level Timeline

First draft of TEFCA released January 2018 (AIRA members submitted comments)



ONC TEFCA User's Guide: https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf, accessed 5/22/2019

Comments of Support – Push Use Case Added

- Page 14: Additionally, ONC received a number of requests from commenters to include a "push-based" exchange modality in the TEF and the Common Agreement. ***Commenters noted that push transactions play a vital role in supporting transitions of care and public health use cases and would be necessary to fully support required Public Health reporting.*** Therefore, ONC has included QHIN Message Delivery, which supports instances where a QHIN sends EHI to one or more QHINs for delivery. We request comment on the inclusion of QHIN Message Delivery and its definition.

- **Comment:** We **strongly** support the addition of the "push" use case to TEFCA Draft 2.

Comments of Support – Public Health Inclusion

- Pg. 10: The TEF and the Common Agreement follow a "network of networks" structure, which allows for multiple points of entry and is inclusive of many different types of health care stakeholders. Such stakeholders include, but are not limited to:
  - …Public Health Agencies…
- **Comment:** We appreciate the continued explicit inclusion of public health as a key stakeholder and important contributor to the TEFCA concept.

Comments of Support – Supporting Materials

- General: To help further explain the new TEFCA draft, ONC has provided a User's Guide slide deck, plus a series of 2-page information sheets for different stakeholder groups including state government and public health.

- **Comment:** The document continues to read well, and the supporting material from ONC is well written and useful.

Comments of Support – Hierarchy of Standards

- Pg. 25: Specifically, HINs should first look to use standards adopted by HHS, then those approved by ONC through the proposed standards version advancement process as part of the ONC Health IT Certification Program (Certification Program), and finally, those identified in the ISA. In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders…
- **Comment:** This is helpful to organize adherence to standards in a prioritized order.

Comments of Support: Timeline

- Pg. 20: QHINs have *12 months* to update agreements and technical requirements.

Was changed to:

- QHINs have *18 months* to update agreements and technical requirements.

- **Comment:** We support the longer timeline, and believe it to be more reasonable and attainable.

Comments of Concern: Voluntary Participation

- Pg. 9: ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply.
- **Comment:** This wording seems ambiguous. Is adherence to the MRTCs really voluntary for QHINs? Clarification would be helpful.

Comments of Concern: QHIN Flexibility

- Pg. 14: As such, the TEF, MRTCs, and QTF do not dictate the internal requirements or business structures of QHINs, but rather provide QHINs flexibility to provide different services and support different stakeholders.
- **Comment:** While it is important to not micro-manage the activities of QHINs, there may be reason for concern if each QHIN requires adherence to different standards and processes. Some stakeholders, most notably Health IT developers, may need to support participation in multiple QHINs and would be burdened by variations in requirements. We encourage the development of some basic “rules of the road” for intra-QHIN exchanges.

Comments of Concern - Standards

- **General Comment:** Most of the standards (both content and transport) in the document are QHIN to QHIN requirements. TEFCA doesn't appear to be explicit regarding QHIN-to-Participant or Participant-to-Participant Member. It's unclear what the vision is for those exchanges. Are they going to remain using their tried-and-true methods or will they be required to transition to QHIN preferred standards? This would be a considerable lift for IIS (which would require significant funding and time to implement).

(related to previous comment)

Comments of Concern: QHIN Technical Framework

- Pgs. 9-10: This Common Agreement would be based on the TEF noted above and would be comprised of three parts:
  - MRTCs, ARTCs, and the QHIN Technical Framework

But:

- Pg. 34: The Common Agreement shall consist of (a) the Minimum Required Terms and Conditions, (b) the Additional Required Terms and Conditions, and (c) such other terms as the RCE and the QHIN mutually agree upon;

- **Comment:** The document should be consistent in this regard.

Comments of Concern: Security Labeling

- Pg. 19: Labeling shall occur at the highest (document or security header) level.

- **Comment:** The ONC proposed rule calls for security labeling at a more granular level. Should these two proposals by harmonized?

Comments of Concern – Security Labeling

- Pg. 19: Currently, security labels can be placed on data to enable an entity to perform access control decisions on EHI such that only those persons appropriately authorized to access the EHI are able to do so. ONC is considering the inclusion of a new requirement regarding security labeling that states the following:
  - At a minimum, such EHI shall be electronically labeled using the confidentiality code set as referenced in the **HL7 Version 3 Implementation Guide**: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata;
- **Comment:** It's not clear where/how this HL7 V3 code set would be used in non-V3 EHI exchanges such as V2 or FHIR. Also, please clarify what "at a minimum" means. Are there examples of things that are better than this suggested floor which could be used?

Comments of Concern: Termination of Participation

- Pg. 46: 2.2.12 Termination of Participation in the Common Agreement. In the event that a QHIN's Common Agreement is terminated due to a material breach of its terms by the QHIN without cure, then the QHIN shall, to the extent required by the Common Agreement, return or destroy all EHI received from, created by, or received by the QHIN that the QHIN still maintains in any form and retain no copies of such EHI except as provided below.

- **Comment:** The document outlines requirements upon the termination of a QHIN from the Common Agreement, but there is no mention of the QHIN's relationship to Participants and Individual Users in this case. Are the Participants and Individual Users released from any obligations to the QHIN? If the Participants or Individual Users were required to pay any upfront fees for joining the QHIN, are those fee refunded? Clarification might be helpful.

Comments of Concern: Fees

- Pg. 48: 5.2.1: Reasonable and Non-Discriminatory Fees. A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN. Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.

- **Comment:** This section seems to contain two contradictory statements. The first sentence (A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN.) implies that a QHIN may impose a fee on another QHIN. Yet the second sentence (Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.) seems to say that no QHIN is obligated to pay such a fee. Please clarify this meaning of this section.

Comments of Concern: Fees

- Pg. 20: QHINs *may not* charge other QHINs to respond to queries for Individual Access, Public Health, or Benefits Determination.

Was changed to:

- QHINs *may not* impose any other fee on the Use or further Disclosure of the EHI once it is accessed by another QHIN.
- **Comment:** It is not clear what the implication is if Public Health related queries are not exempted from fees. Does this mean that a Public Health entity may need to pay for access to data held by QHINs and their participants? Does this mean that a Public Health entity may charge users for access to data held by the entity? Given the important role Public Health data plays in maintaining healthy populates, restoration of the prior wording may be appropriate.

Comments of Concern: Standards

- Pg. 72: A QHIN Query typically involves two major workflows, patient discovery via IHE XCPD and document location/retrieval via IHE XCA.
- **Comment:** These sections outline the adoption of IHE profiles but not FHIR or other existing standards
  - Many existing data exchanges in Public Health use standards other than IHE profiles. If the emphasis is to be on “existing, deployed technical infrastructure” than the adoption of existing HL7 v2, CDA and FHIR standards should be required. As well, given the focus of the ONC and CMS proposed rules on FHIR, adoption of FHIR within TEFCA should be a priority.

Comments of Concern - Definitions

- **General Comment:** As in the ONC Notice of Proposed Rule Making (NPRM), there is some confusion in the definition of Electronic Health Information (EHI). It is critical that this key definition and its relationship to the emerging US Core Data for Interoperability (USCDI) be reconciled.

Comments of Concern – Definition of HIN, QHIN

- Pg. 34-35: **Health Information Network (HIN):** an individual or an entity that satisfies one or both of the following-

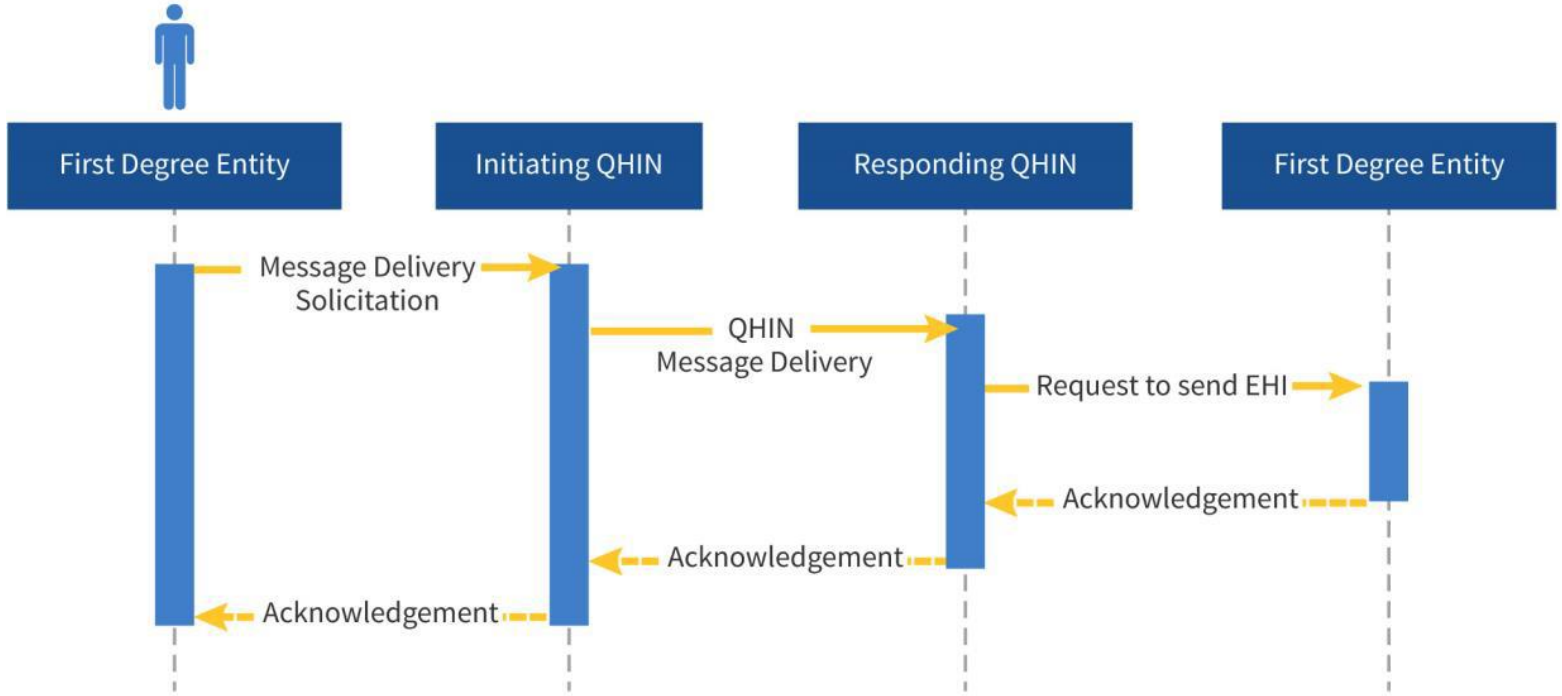
  1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; or

  2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

- **Comment:** The definition of who could be a HIN or QHIN is vague – unclear on if an IIS or local health department would/could/should qualify? Also unclear how many QHINs ONC envisions operating at one time.

Comments of Concern - Messaging

Pg. 82:



Comment: We appreciate that acknowledgment messaging is called out in the actual TEFCA document, but it does not appear in the user guide. We want to ensure that a response to a submitted message is always required.

Comments of Concern - Messaging

- Pg. 82: Specified standards for Message Delivery are included in *Table 8*…
- Responding QHIN(s) MUST be capable of processing XCDR transactions to send documents and associated metadata to the appropriate First Degree Entity(ies)

Table 8. Specified & Alternative Standards for Message Delivery		
Function	**Specified Standard / Profile**	**Alternative / Emerging Standard / Profile**
Message Delivery	• IHE XCDR	• Direct • HL7 FHIR RESTful API

- **Comment:** The standards referenced are IHE XCDR profile to get the data from QHIN A to QHIN B, but it doesn't define the standards on the far left and far right of the swim lane. It does use the word "document and associated metadata", which is concerning. We would prefer this to be message (and not document). Messages = V2. Documents = V3 and/or CDA. At minimum it should include both messages and documents.

Comments of Concern - Matching

- Pg. 82: Initiating QHINs MUST be capable of receiving Message Delivery Solicitations from a First Degree Entity

- **Comment:** It is not clear who is responsible for consolidation, deduplication, verification, reconciliation into the new system, etc. Do these activities all happen at the smart phone app (in this example)? There are some critical policy/functional decisions and standards which need to be put in place to both reduce variation and safeguard disclosures when incorrect patient matches are made during queries.

Comments of Concern – Matching

- Pg. 28: To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to accurately match data.
- **Comment**: The issue of patient matching across the healthcare ecosystem continues to be a serious obstacle to interoperability. The description of patient matching for query purposes within the MRTC presents a rather simplistic view of patient matching, with no recognition of the complexity of uncertain matches, multiple matches, and similar issues. The Patient Identity Resolution section of the QTF does detail more expectations of a QHIN in this area but offers no real solutions to the difficulties we all experience.

Comments of Concern – HIPAA and Security

- Pg. 16 - In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape.
- **Comment:** It is not clear what this might mean for non-covered entities in Public Health and the Public Health exclusion for HIPAA disclosures – please articulate more fully. We would recommend an explicit exclusion for non-covered entities in Public Health.

Comments of Concern – Individual Access Services

- Pg. 15: The Exchange Purpose described as Individual Access in TEF Draft 1 has been modified to Individual Access Services, which includes the HIPAA Privacy Rule **right for an individual to view or obtain a copy of his or her Protected Health Information from Covered Entities**. The Individual Access Services Exchange Purpose now includes a **corresponding requirement for non-HIPAA entities** that elect to participate in the Common Agreement. We request comment on the scope of these Exchange Purposes.
- **Comment**: There is some ambiguity regarding the provisions for Individual Access Services and whether a public health registry is *required* to respond to such a request if it is unable or unwilling to do so. TEFCA clearly states that a response is not necessary if such a response would be against the law (as it is in some jurisdictions). Normally, response to Individual Access Services requests is based on the requirement under HIPAA for covered entities (CE) and their business associates (BA) to provide a patient with his/her EHI on request; the TEFCA draft (in section 7.14(ii)) makes this requirement to respond incumbent on all participants whether they are CEs/BAs or not. Some public health laws and rules do not allow individuals to access their own data or restrict how access is obtained (Example: a state rule requires the patient to come in person with photo ID for identity proofing). We request that public health be provided a specific exemption from this requirement as HIPAA does. A suggestion is to update 8.21 on page 67 to extend the exemption provided to federal agencies there to state and local agencies.

Comments of Concern – Meaningful Choice, Mandates, State Law

- Pg. 17: Therefore, the MRTCs Draft 2 requires that QHINs, Participants, and Participant Members provide Individuals with the opportunity to exercise Meaningful Choice to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law.
- **Comment**: It seems confusing to say that local law supersedes TEFCA, but an entity that participates must abide by their Common Agreement. There is also a lack of clarity about right to opt out vs required reporting laws, and where patient consent is stored. It would be very difficult to reconcile those competing concerns across state lines. These issues suggest that there may be a level of detail not yet identified or addressed in these documents.

Comments for Discussion – Removal of Population Health

- Pgs. 13-14: TEF Draft 1 required that QHINs support three types of exchange modalities for exchanging EHI — Targeted Query, Broadcast Query, and Population-Level Data Exchange….However, commenters expressed concern regarding the relative maturity of Population-Level Data Exchange. While important for modern health care delivery and to the Cures Act's long term goals for quality measurement, risk analysis, research, and public health, the industry is still working to mature this use case in a network exchange context. Therefore, this use case has been removed from the MRTCs.
- **Comment:** Population level data (particularly geographic populations) is of critical importance to public health and we encourage ONC to include explicit population query requirements as soon as feasible. Until such time, it is critical that TEFCA not introduce barriers to population level data exchange by authorized parties. We strongly support the inclusion of population-level data exchange in the principles of the Trusted Exchange.
- **Question**: Is the broader community concerned about the removal of population level data as a modality?

Additional Comments, Questions?

Next Steps

Week of May 28: Compiled DRAFT comments shared with IIS community

June 3: Edits on DRAFT comments due back to AIRA – send to Kim Rutland at krutland@immregistries.org

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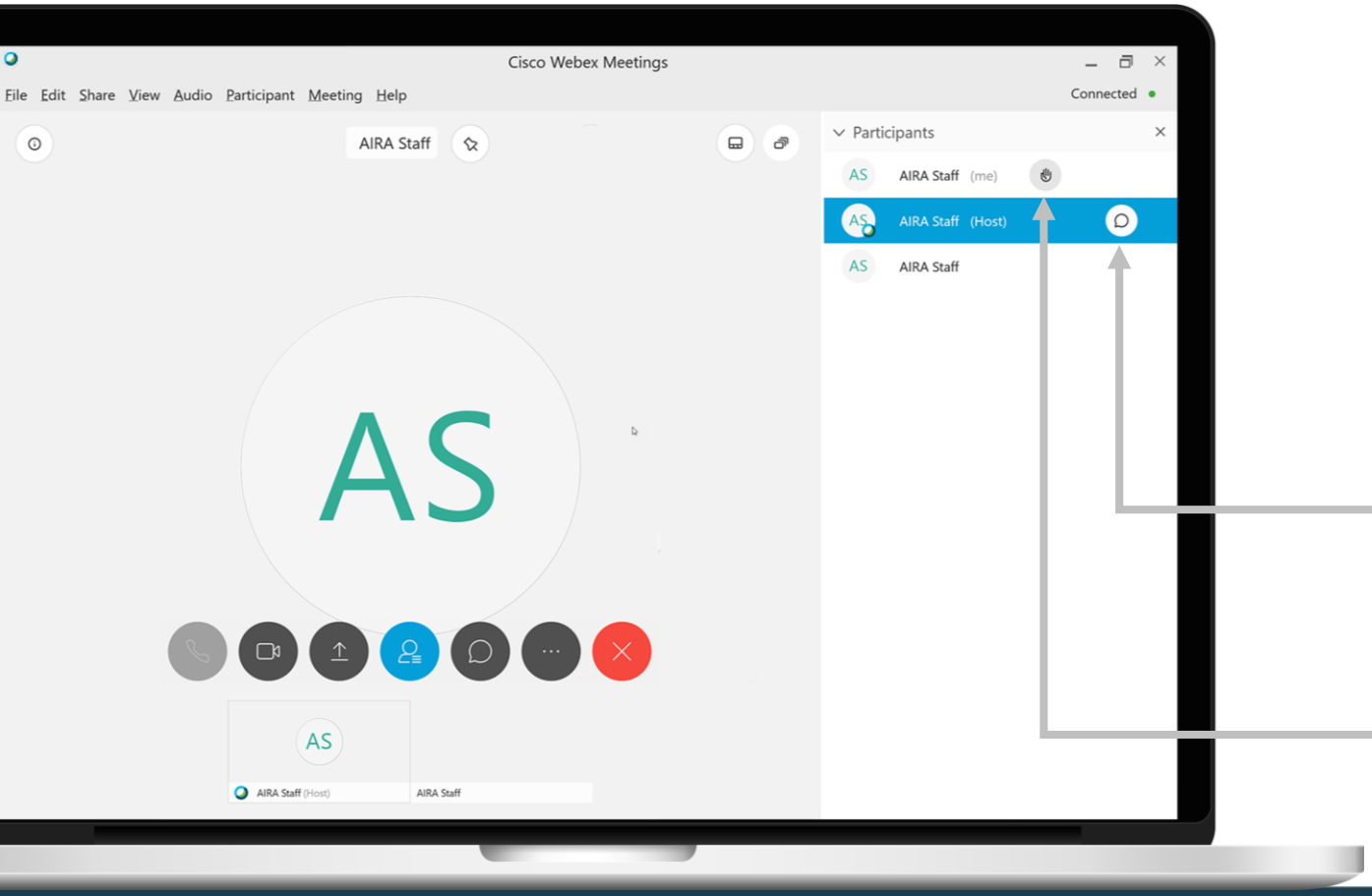
Questions, Comments, Discussion?



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Thank You!

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