Elements of the Common Agreement: Closer Look # 2

October 5, 2021

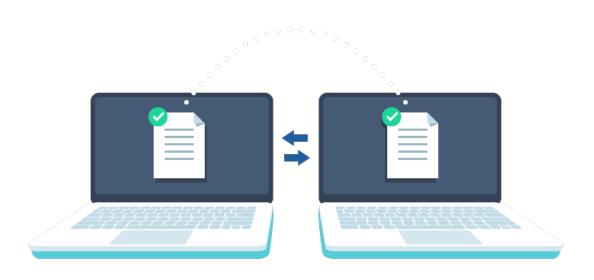


This project is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under 90AX0026/01-00 Trusted Exchange Framework and Common Agreement (TEFCA) Recognized Coordinating Entity (RCE) Cooperative Agreement. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.



Agenda

- Welcome and Brief Overview
- Closer Look #2 Topics:
 - Individual Access Services
 - Governing Approach
 - Change Management
 - RCE Directory Service
 - Fees
- Opportunities for Stakeholder Feedback
- Questions and Answers





Meet the RCE Team



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TEFCA Goals



GOAL 1

Establish a floor of universal interoperability across the country



GOAL 2

Create simplified nationwide connectivity



GOAL 3

Provide the infrastructure to allow individuals to gather their data

Simplified connectivity for individuals, health care providers, health plans, public health agencies, and other stakeholders.

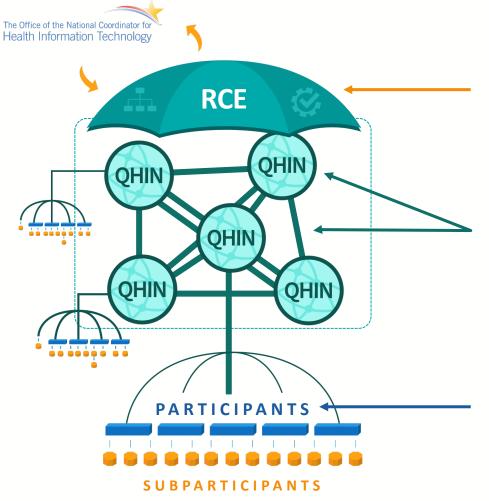


Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021 **During 2022** Calendar Q1 of 2022 • Public engagement webinars. •QHINs begin signing Common Release Final Trusted •Common Agreement (CA) Work Group sessions. Agreement. Exchange Framework, CA V1 •RCE and ONC use feedback to finalize CA V1 and QHINs selected, onboarded, and Final, and QTF V1 Final. QHIN Technical Framework (QTF) V1. begin sharing data on rolling basis. Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 2023 2021 2022



How Will TEFCA Work?



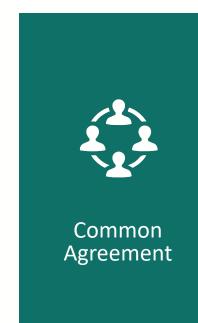
RCE provides oversight and governance for QHINs.

QHINs connect directly to each other to facilitate nationwide interoperability.

Each QHIN represents a variety of Participants that they connect, serving a wide range of Subparticipants.



TEFCA Elements





Standard Operating Procedures











The Common Agreement

- The Common Agreement would establish the infrastructure model and governing approach for users in different information exchange networks to securely share clinical information with each other—all under commonly agreed-to expectations and rules, regardless of which network they happen to be in.
- The Common Agreement will be a legal document that each QHIN signs with the RCE.
- Some provisions of the Common Agreement will flow down to other entities (Participants and Subparticipants) via other agreements.
- The Common Agreement will incorporate the QHIN Technical Framework and the Standard Operating Procedures (SOPs).







Elements of the Common Agreement



- Definitions
- 2. Exchange Purposes
 - Requests
 - Uses and Disclosures
 - Responses
- 3. Participants and Subparticipants
- 4. Required Flow-Down Provisions
- 5. TEFCA Information and Required Information

- 6. Governing Approach to Exchange Activities Under the Common Agreement
- 7. QHIN Designation and Eligibility Criteria
- 8. Cooperation and Nondiscrimination
- 9. RCE Directory Service
- 10. Individual Access Services
- 11. Privacy and Security
- 12. Special Requirements (including Consent)
- 13. Fees



Standard Operating Procedures

To provide more specificity on particular issues, the RCE will also develop SOPs on topics such as:



Dispute Resolution Process



Governing Approach (Governing Council, Transitional Council, Advisory Groups)



Conflicts of Interest



QHIN Eligibility Criteria, Onboarding, and Designation



QHIN Security
Requirements for the
Protection of TEFCA
Information

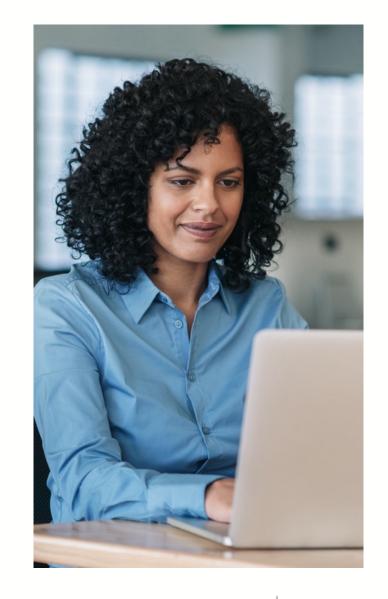
Standard Operating Procedure(s) or **SOP(s)**: a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into the Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes.

Closer Look #2 Topics



Individual Access Services (IAS)

- IAS would be the services any QHIN, Participant, or Subparticipant provide to an Individual to satisfy that Individual's request to access, inspect, or obtain a copy of that Individual's TI that is then maintained by any QHIN, Participant, or Subparticipant.
- A QHIN, Participant or Subparticipant would be allowed but not required to offer Individual Access Services to Individuals with whom they have a Direct Relationship.





IAS Privacy and Security Requirements

- The Common Agreement would specify the privacy and security requirements that a QHIN, Participant, or Subparticipant would be required to adhere to if it chooses to become an IAS Provider.
 - Includes elements of a written privacy notice for such IAS Providers, which would include a description of the need to obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed by the IAS Provider.
- The Common Agreement would specify Individual rights that IAS Providers would need to provide, such as:
 - The Individual's right to have deleted all of their individually identifiable information maintained by an Individual Access Service Provider and
 - The right to obtain an export of their data in a computable format.





IAS Privacy and Security Requirements (2)

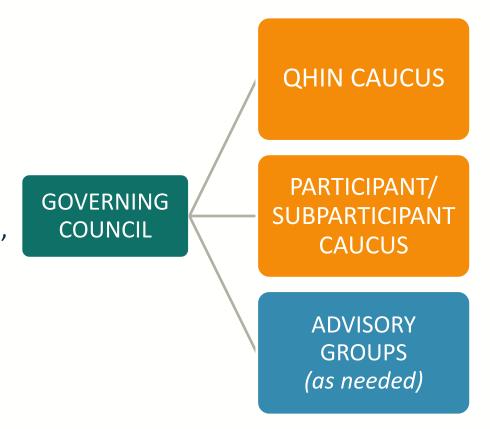
 IAS Providers would need to implement security requirements, including encryption and certain security incident notifications





Governing Approach

- Interim Governance: Transitional Council
- Permanent Governance: Governing Council and Caucuses
- Primary Roles:
 - Resource to the RCE
 - Review proposed amendments to the Common Agreement,
 the QTF, and the SOPs in accordance with the Common
 Agreement's specified change management process
 - Provide oversight for resolution of disputes, following the dispute resolution process that will be part of the Common Agreement
- In addition, ONC oversees the work of the RCE under the Cooperative Agreement





Change Management

- The change management process will allow the RCE and ONC to work with stakeholders to update, implement, and maintain the Common Agreement
- Key function of the governing approach
- ONC approval is required for amendments to the Common Agreement, the SOPs, and the QTF





RCE Directory Service

- The RCE would maintain an RCE Directory Service to support exchange of information between and among QHINs, Participants, and Subparticipants.
- The Common Agreement would identify the rights and limits of use to the RCE Directory Service. For example, the information contained in the RCE Directory Service is prohibited from being used for marketing purposes unless that marketing is merely incidental to an effort to expand or improve connectivity via the Common Agreement.
- The QTF specifies expectations for QHINs to access and contribute to the RCE Directory Service.





Fees

- The Common Agreement is expected to include a provision that prohibits a QHIN from charging fees to other QHINs with respect to activities under the Common Agreement.
- 2. QHINs would not be prohibited from charging fees to Participants.





The RCE is specifically seeking input on the issue of fees.



Opportunities for Stakeholder Feedback



Opportunities for Stakeholder Feedback on Elements of the Common Agreement

Webinar Series:

- Overview; Cooperation and Nondiscrimination; Exchange Purposes and Related Definitions (September 21)
- Closer Look Topics #1: Permitted Requests, Uses, and Disclosures;
 Required Responses and Required Information (including Consent); Privacy and Security (September 29)
- Closer Look Topics #2: Individual Access Services; Governing Approach;
 Change Management; RCE Directory Service; Fees (October 5)
- Closer Look Topics #3: QHIN Designation and Eligibility Criteria (October 14)

Common Agreement feedback form on the RCE website open until October 21

https://rce.sequoiaproject.org/common-agreement-elements-feedback-form/ or email us at rce@sequoiaproject.org



All feedback submitted to the RCE will be made publicly available on the RCE's and/or ONC's website, including any personally identifiable or confidential business information that you include in your feedback. Please do not include anything in your feedback submission that you do not wish to share with the general public.



Opportunities for Stakeholder Feedback

General Sessions:

- Presentation to the Health IT Advisory Committee (October 13)
- October 19 Monthly Informational call

QHIN Technical Framework (Recorded webinars):

- QHIN Technical Framework Overview
- Essential Elements of QTF: A Technical Overview



Sign up for webinars at: https://rce.sequoiaproject.org/



Questions?Email us at rce@sequoiaproject.org





Questions & Answers