

Elements of the Common Agreement: A Closer Look #1

September 29, 2021

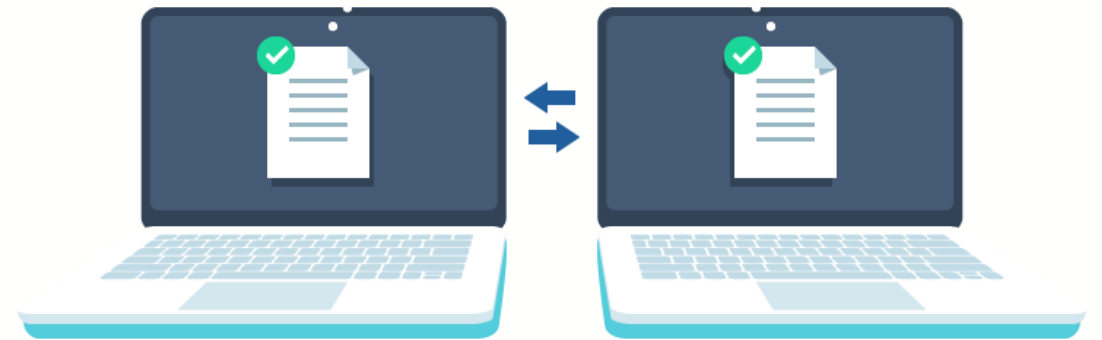


ONC
TEFCA
RECOGNIZED
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ENTITY

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
- A Closer Look #1 Topics:
 - Permitted Requests, Uses, and Disclosures
 - Required Responses and Required Information (including Consent)
 - Privacy and Security
- Timeline for Implementation and 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

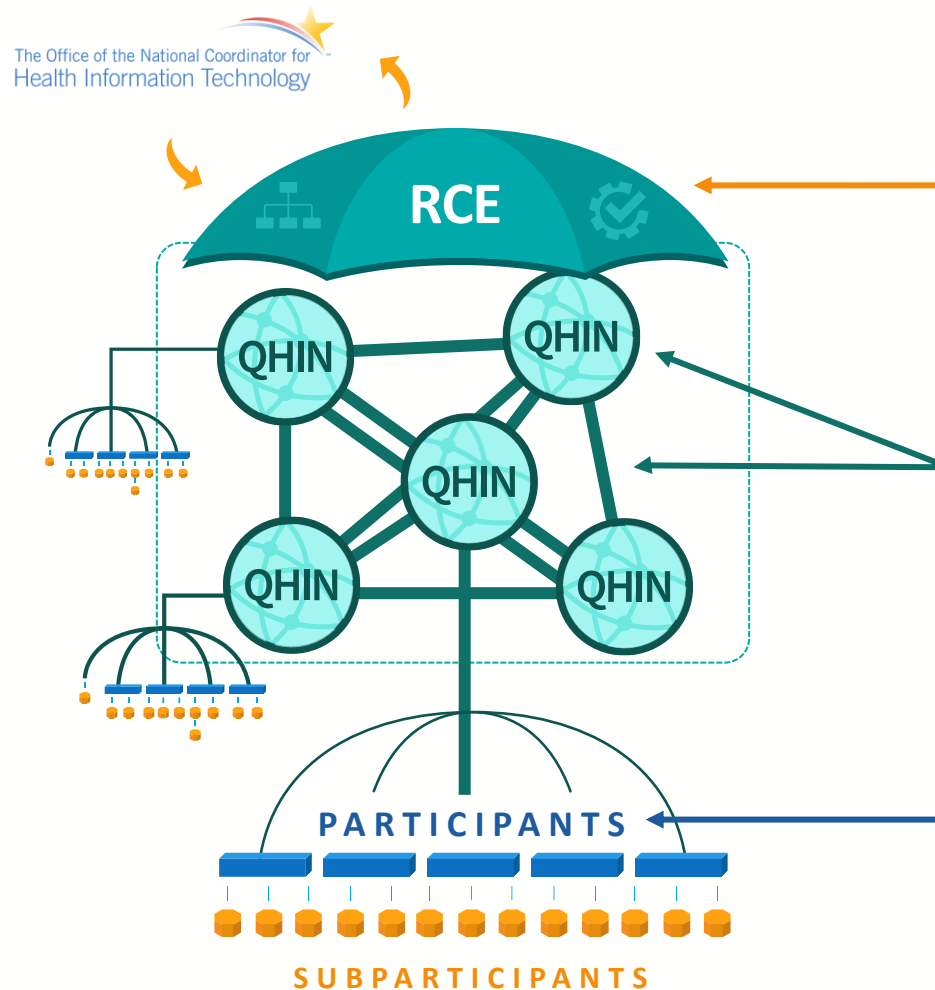


GOAL 3

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.

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, and may serve a wide range of Subparticipants.

TEFCA Elements



Common Agreement



Standard Operating Procedures



QHIN Technical Framework



QHIN Onboarding



Metrics



Governance

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).



The RCE welcomes stakeholder feedback.

Elements of the Common Agreement



1. 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

A Closer Look #1 Topics

Exchange Purposes

- The term Exchange Purposes identifies the reasons for which information could be requested and shared through QHIN-to-QHIN exchange
- At this time, only the six Exchange Purposes described above would be allowed under the Common Agreement
- The RCE plans to work with stakeholders to identify additional Exchange Purposes over time
- QHINs must support all Exchanges Purposes

Permitted Exchange Purposes



Treatment



Payment



Health Care Operations



Public Health



Benefits Determination



Individual Access Services

Requests, Uses and Disclosures

- TEFCA **requests** would be transmitted via a QHIN's Connectivity Services and consistent with the requirements of the QTF.
- Only certain QHINs, Participants, or Subparticipants could make requests for each Exchange Purpose. Specifically, a **QHIN, Participant, or Subparticipant may only request, Use, or Disclose TEFCA Information for a specific Exchange Purpose if the QHIN, Participant, or Subparticipant is the type of person or entity that is described in the definition of the applicable Exchange Purpose.**
- **Uses and Disclosures** would adhere to the Common Agreement privacy and security requirements and any applicable privacy notices.



Responses



- In most cases, QHINs, Participants, and Subparticipants would be required to respond to a request for certain health information for any of the Exchange Purposes. Responses would not be required by the Common Agreement if providing the information is prohibited by Applicable Law or the Common Agreement.
- There would be **specific exceptions** where a response is permitted but not required by the Common Agreement:
 - If Signatory is a Public Health Authority;
 - If Signatory is a governmental agency that determines non-health care benefits, including such an agency’s agent(s)/contractor(s);
 - If Signatory is a Non-HIPAA Entity provider of Individual Access Services;
 - If the reason asserted for the request is Individual Access Services and the information would not be required to be provided to an Individual pursuant to 45 CFR § 164.524(a)(2), regardless whether Signatory is a Non-HIPAA Entity, a Covered Entity, or a Business Associate;
 - If the requested information is not Required Information (as described in Section 5 “TEFCA Information and Required Information” below), provided such response would not otherwise violate the terms of this Common Agreement; or
 - If Signatory is a federal agency, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law (e.g., it is Controlled Unclassified Information as defined at 32 CFR Part 2002 and the party requesting it does not comply with the applicable policies and controls that the federal agency adopted to satisfy its requirements)

Privacy

- Most connected entities will be HIPAA Covered Entities or Business Associations of Covered Entities, and thus already be required to comply with HIPAA Privacy, Security, and Breach Notification Rule requirements.
- The Common Agreement would require non-HIPAA Entities to protect TEFCA Information that is individually identifiable in substantially the same manner as HIPAA Covered Entities protect PHI, including having to comply with the HIPAA Security Rule and most provisions of the HIPAA Privacy Rule

TEFCA will promote strong privacy protections.



Security



- QHINs will be expected to meet a high bar for security, including:
 - Third-party certification to an industry-recognized cybersecurity framework
 - Annual security assessments
- Flow-down contract provisions for all Participants and Subparticipants, to undertake:
 - At a minimum, security measures that align with the HIPAA Security Rule, even if they are not HIPAA Covered Entities or Business Associates
- Security incident notifications affecting QHIN-to-QHIN exchange that would
 - Apply to QHINs
 - Flow down to Participants and Subparticipants.
- Designed to avoid conflict with Applicable Law and duplicative notification requirements
- The RCE would actively facilitate security activities, with the support of a Cybersecurity Council drawn from participating QHINs

TEFCA will promote strong security protections.

Special Requirements (including Consent)

- The Common Agreement would not require QHINs, Participants, and Subparticipants that are not IAS Providers to obtain Individual consent to Use or Disclose TI except to the extent they would be required to do so under Applicable Law. The HIPAA Privacy Rule permits, but does not require, a Covered Entity to obtain patient consent for Uses and Disclosures of Protected Health Information for Treatment, Payment, and Health Care Operations activities.
- The Common Agreement would require IAS Providers to obtain express consent from Individuals for, among other things, how the Individual's information may be accessed, exchanged, Used, and/or Disclosed, including whether that information may be sold.
- Many municipal governments and states have laws that require patient consent. If municipal or state law requires that an Individual's consent be obtained before a health care provider Discloses an Individual's identifiable information for Treatment, then the Common Agreement does not change that requirement. Such a provider would obtain consent from an Individual before disclosing that Individual's information to others under the Common Agreement. Furthermore, given the state law, the provider would not be required to respond to TEFCA Information requests if that provider has not obtained the proper consent.
- In situations where consent documents may be shared, the QTF has proposed a mechanism for QHINs, Participants, Subparticipants, and Individuals to share such electronic documents with each other.
- The Common Agreement would not supersede a Covered Entity's obligations under the HIPAA Privacy Rule to obtain an Individual's authorization (as defined in the HIPAA Privacy Rule) when required.

Timeline for Implementation and Opportunities for Stakeholder Feedback

Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021

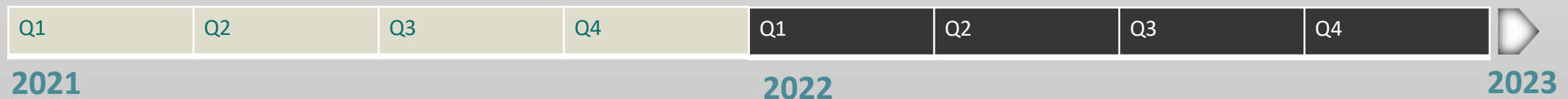
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

Calendar Q1 of 2022

- Release Final Trusted Exchange Framework, CA V1 Final, and QTF V1 Final.

During 2022

- QHINs begin signing Common Agreement.
- QHINs selected, onboarded, and begin sharing data on rolling basis.



Opportunities for Stakeholder Feedback on Elements of the Common Agreement

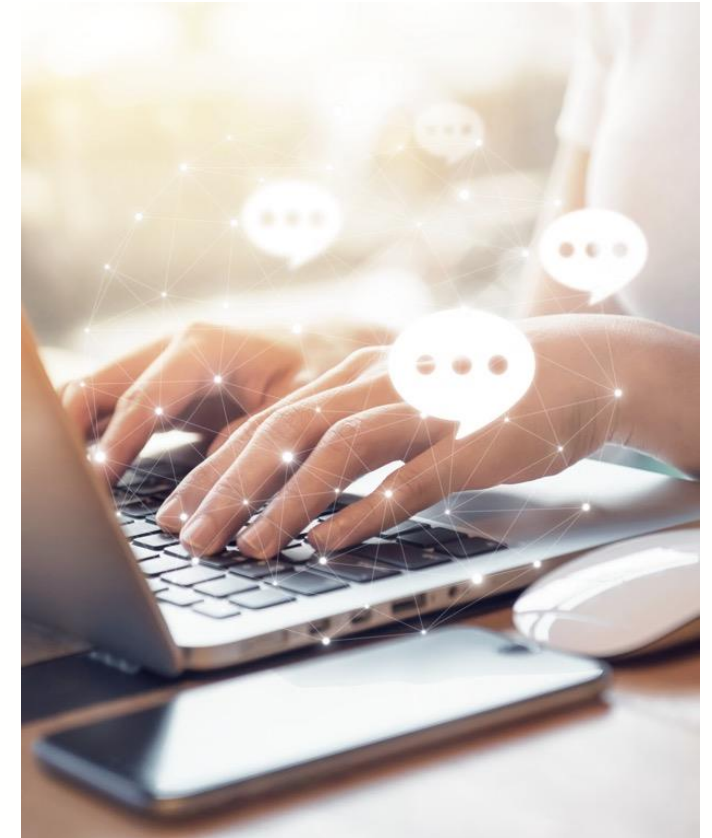
Webinar Series:

- 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: QHIN Designation and Eligibility Criteria; Governing Approach; Change Management; Fees; Confidentiality and Accountability (October 5)
- Closer Look Topics #3: Individual Access Services; RCE Directory Service (October 14)

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

<https://rce.sequoiaproject.org/common-agreement-elements-feedback-form/>

Or e-mail: 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