

Elements of the Common Agreement: An Overview

September 21, 2021

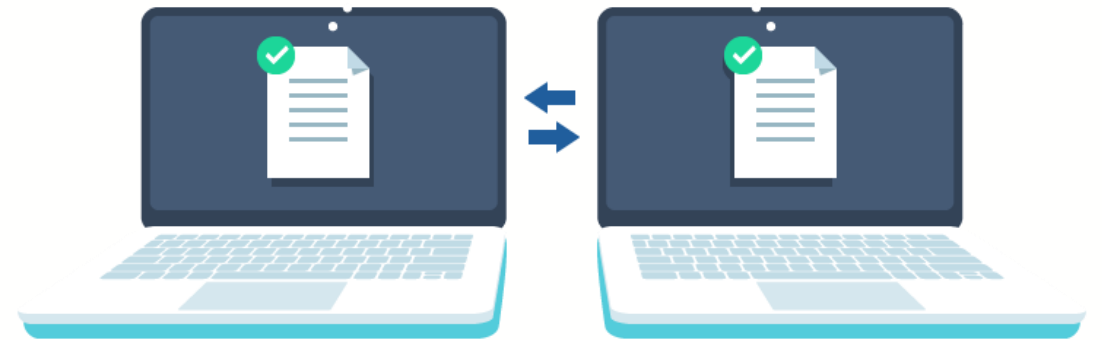


ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

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
- CURES Act and TEFCA: A Brief History
- Components of a Trusted Exchange Framework and Common Agreement
- Elements of the Common Agreement
- Timeline for Implementation and Opportunities for Stakeholder Feedback
- Questions and Answers



Meet the RCE Team



Mariann Yeager
CEO
The Sequoia Project



Alan Swenson
Executive Director
Carequality



Steve Gravely
Founder & CEO
Gravely Group



Cait Riccobono
Attorney
Gravely Group



Chantal Worzala
Principal
Alazro Consulting

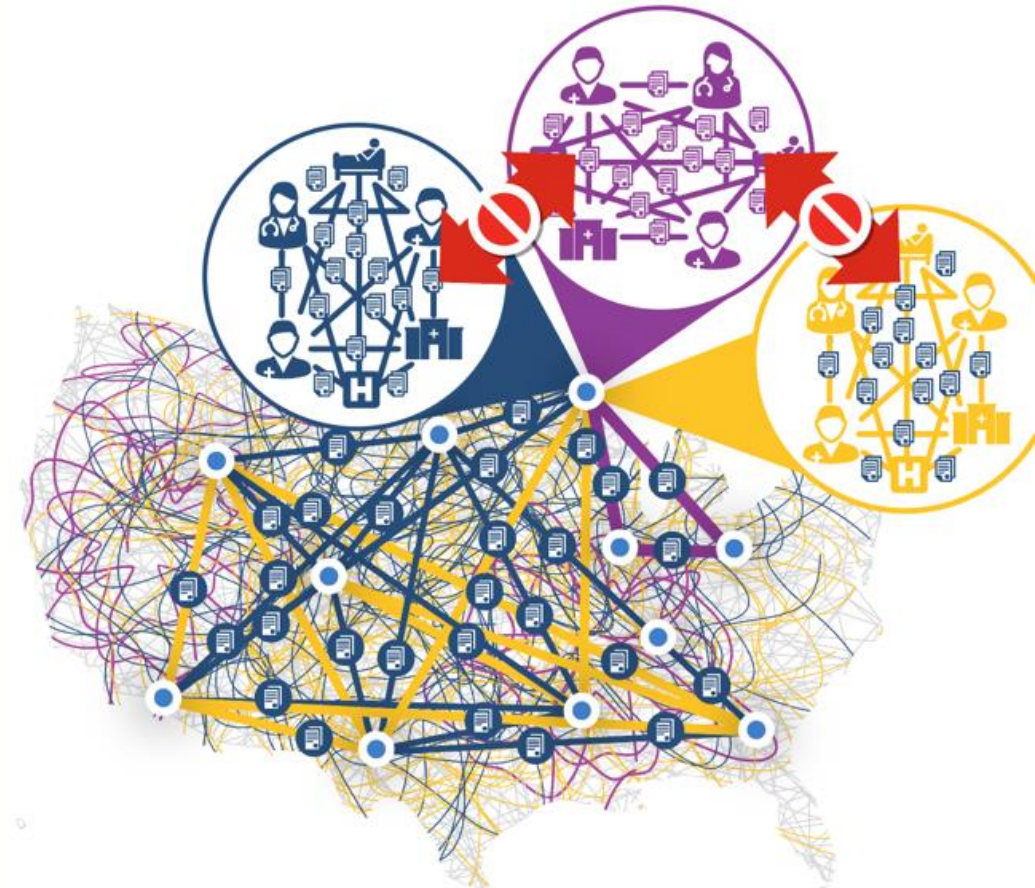
CURES Act and TEFCA: A Brief History

Why do we need the Trusted Exchange Framework and Common Agreement (TEFCA)?

COMPLEXITY OF PROLIFERATION OF AGREEMENTS

Many organizations have to join multiple Health Information Networks (HINs), and most HINs do not share data with each other.

Trusted exchange must be simplified in order to scale.



21st Century Cures Section 4003(b)

*“[T]he National Coordinator shall convene appropriate public and private stakeholders to **develop or support a trusted exchange framework** for trust policies and practices and for a **common agreement** for exchange between health information networks.” [emphasis added]*



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 data

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

Benefits of TEFCA

Relevant, trusted
information from
nationwide sources



Consumers

Access their own records from sources located across the nation.



Providers and health systems

Obtain complete picture of care across settings to improve care and coordination with fewer connection points.



State programs and public health

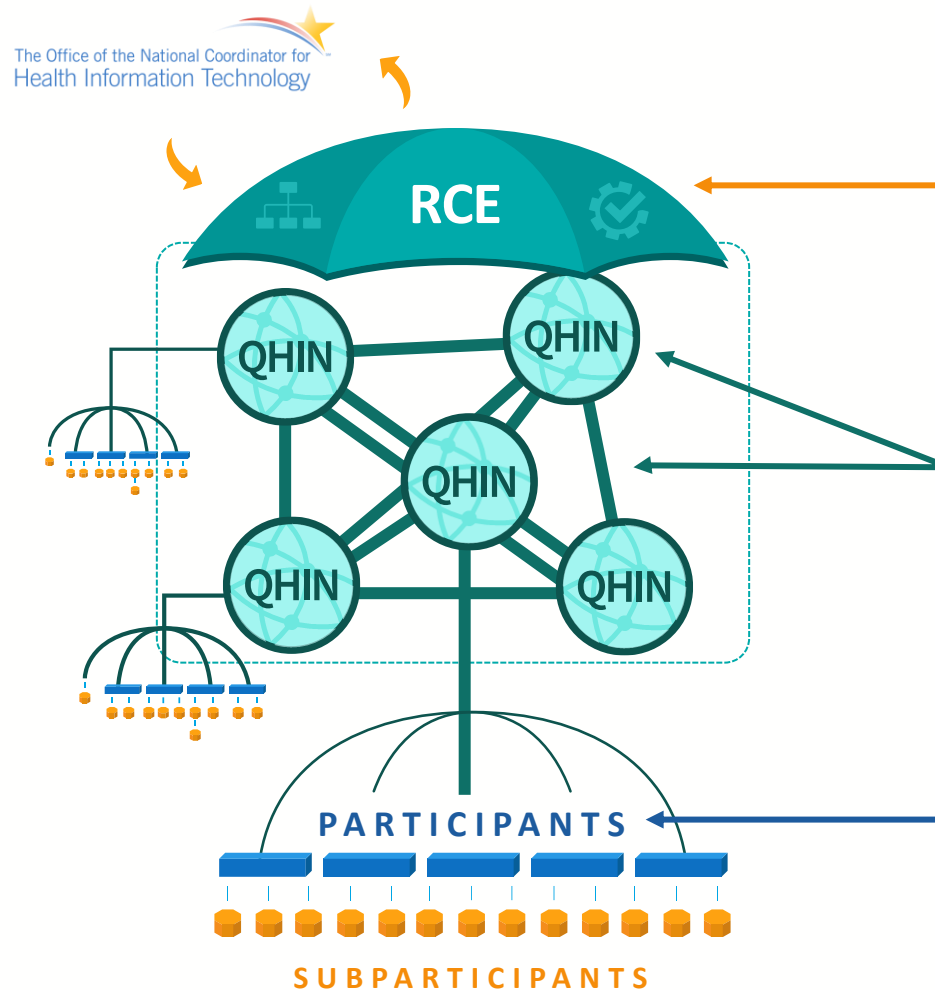
Enhance understanding of health metrics, reduce cost of public health reporting and program management.



Payers

Get and share data needed for care management, value-based care, etc.

How Will TEFCA Work?



RCE provides oversight and governance for QHINs.

QHINs connect directly to each other to facilitate nationwide interoperability.

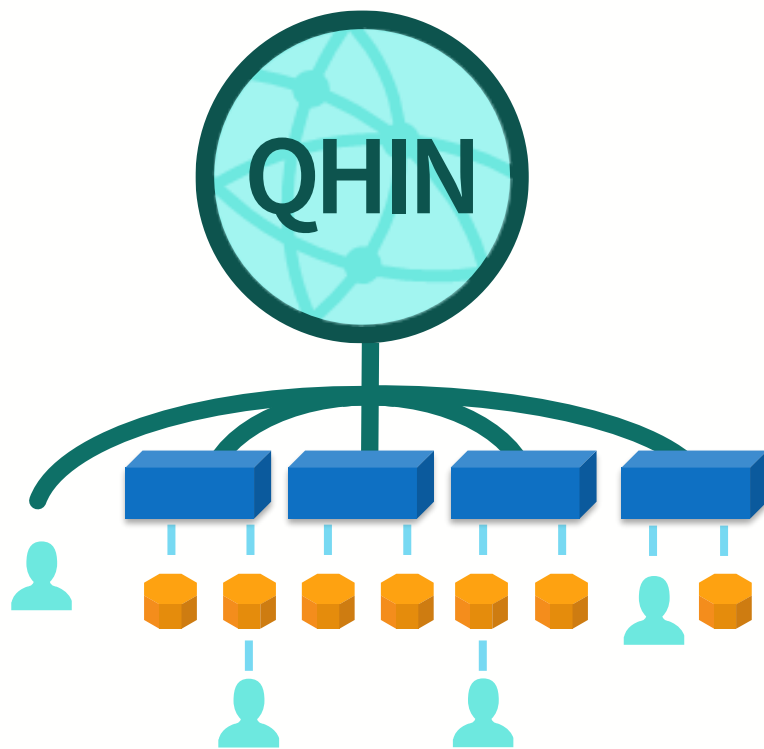
Each QHIN represents a variety of Participants that they connect, serving a wide range of Subparticipants.

Recognized Coordinating Entity (RCE)



- Develop, update, implement, and maintain the Common Agreement.
- Modify and update the QHIN Technical Framework.
- Virtually convene public stakeholder feedback sessions.
- Identify, designate, and monitor Qualified Health Information Networks (QHINs).
- Develop and maintain a process for adjudicating QHIN noncompliance.
- Propose strategies to sustain the Common Agreement at a national level.

Structure of a Qualified Health Information Network (QHIN)



Participant

a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive TEFCA Information (TI) via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes. Without limitation of the foregoing, a health information exchange, health IT developer, health care system, payer, or federal agency could each be a Participant.

Subparticipant

a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either: (i) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive TI or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used to send and/or receive TI.

Individual

one or more of the following:

1. An individual as defined by 45 CFR 160.103;
2. Any other natural person who is the subject of the TEFCA Information being requested, Used, or Disclosed;
3. A person who legally acts on behalf of a person described in paragraphs (1) or (2) of this definition in making decisions related to healthcare as a personal representative, in accordance with 45 CFR 164.502(g);
4. A person who is a legal representative of and can make healthcare decisions on behalf of any person described in paragraphs (1) or (2) of this definition; or
5. An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (1) or (2) of this section or the individual's estate under Applicable Law.

Certain Provisions of the Common Agreement will flow down to Participants and Subparticipants

What Kinds of Exchange Will be Supported?

Initial Exchange Modalities:

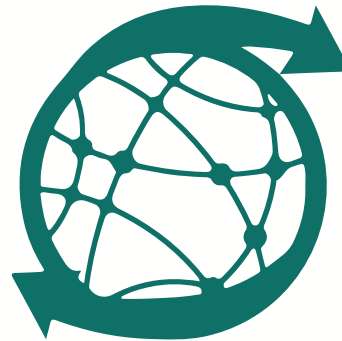
- QHIN query
- QHIN message delivery

Primary Data Exchanged:

- Available electronic health information in C-CDA 2.1, including the US Core Data for Interoperability (USCDI)

Potential Future Additions:

- Population-level data exchange
- FHIR-based exchange
- Additional exchange purposes, use cases, and exchange modalities based on industry need and input



Exchange Purposes:

- Treatment
- Payment
- Health Care Operations
- Public Health
- Benefits Determination
- Individual Access Services

Elements of the Common Agreement

TEFCA Elements



Common Agreement



Standard Operating Procedures



QHIN Technical Framework



QHIN Onboarding



Metrics



Governing Approach

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.

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.

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

Common Agreement: Key Definitions

TERM	DEFINITION
TEFCA Information (TI)	any information that is exchanged between QHINs for one or more of the Exchange Purposes pursuant to any of the Framework Agreements.
Exchange Purpose(s)	means the reason for a request, Use, Disclosure, or response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Standard Operating Procedure (SOP) adopted after _____, 202____, each to the extent permitted under Applicable Law, under all applicable provisions of the Common Agreement, and, if applicable, under the SOP that authorized the Exchange Purpose.
Health Information Network (HIN)	has the meaning assigned to the term “ <i>Health Information Network or Health Information Exchange</i> ” in the Information Blocking Regulations at 45 CFR § 171.102.
Qualified Health Information Network (QHIN)	a Health Information Network that is a U.S. Entity, or non-U.S. Entity if and to the extent permitted by an SOP, that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.

Cooperation and Non-Discrimination

- The Common Agreement would specify expectations of QHINs, Participants, and Subparticipants that would ensure that all parties cooperate in certain aspects of exchange such as:
 - Timely responses to inquiries
 - Notification of persistent and widespread connectivity failures
 - Support in resolving issues
 - Sharing information regarding cybersecurity risks.
- QHINs, Participants, and Subparticipants would be prohibited from limiting interoperability with any other QHIN, Participant, Subparticipant, or Individual in a discriminatory manner.
- The values of cooperation and nondiscrimination form the basis for all of the TEFCA.



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 listed here and described on the following slides 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

Exchange Purposes

- For the purposes of QHIN-to-QHIN exchange, the terms “**Treatment,**” “**Payment,**” and “**Health Care Operations**” generally would have the same meaning as they do under the HIPAA Privacy Rule and would apply to all TEFCA Information, regardless of whether or not the parties to exchange are HIPAA Covered Entities or Business Associates.
- The **Public Health** Exchange Purpose would include requests for Uses and Disclosures of information by Public Health Authorities that are consistent with the HIPAA Privacy Rule and other Applicable Law.
- The **Benefits Determination** Exchange Purpose would support governmental agencies that need information to determine whether a person qualifies for non-health government benefits in a manner that is consistent with the HIPAA Privacy Rule and other Applicable Law.
- The Common Agreement anticipates the use of consumer-facing applications that would assist Individuals in obtaining access to their health information. This Exchange Purpose is called **Individual Access Services**. To the extent permitted by law, Individuals could use an account with a connected consumer-facing application or platform, prove who they are, and request their health information from entities connected via QHIN-to-QHIN exchange.
- Entities will not need to respond to **Individual Access Services** data requests if they meet an exception, which will include, for example, if they are themselves a Non-HIPAA Entity provider of Individual Access Services, or if they are prohibited from doing so by law.



Common Agreement: Exchange Purpose Definitions

TERM	DEFINITION
Treatment	has the meaning assigned to such term at 45 CFR § 164.501.
Payment	has the meaning assigned to such term at 45 CFR § 164.501.
Health Care Operations	has the meaning assigned to such term at 45 CFR § 164.501, except that this term shall apply to a healthcare provider regardless of whether the healthcare provider is a Covered Entity.
Public Health	with respect to the definition of Exchange Purposes, a request, Use, Disclosure, or response permitted under the HIPAA Rules and other Applicable Law for public health activities and purposes involving a Public Health Authority, where such public health activities and purposes are permitted by Applicable Law, including a Use or Disclosure permitted under 45 CFR §164.512(b) and 45 CFR §164.514(e). For the avoidance of doubt, a Public Health Authority may request, Use, and Disclose TI hereunder for the Exchange Purpose of Public Health to the extent permitted by Applicable Law and the Framework Agreements.
Benefits Determination	a determination made by any federal, state, local, or tribal agency, instrumentality, or other unit of government as to whether an Individual qualifies for government benefits for any purpose other than health care (for example, Social Security disability benefits) to the extent permitted by Applicable Law. Disclosure of TI for this purpose may require an authorization that complies with Applicable Law.
Individual Access Services	with respect to the Exchange Purposes definition, the optional services provided, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's TI that is then maintained by or for any QHIN, Participant, or Subparticipant.

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 TI 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”), 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)

Timeline for Implementation and Opportunities for Stakeholder Feedback

Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021

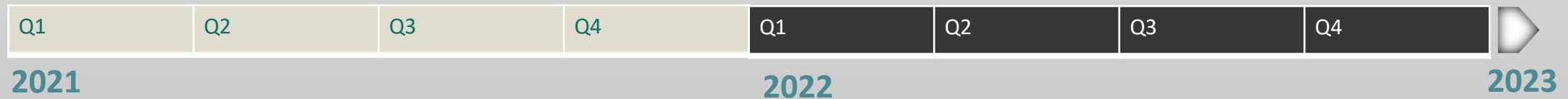
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

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.



What Does All This Mean For You?

Prepare for Participation Under TEFCA

- Follow the RCE work and consider your place in this new ecosystem
 - Join monthly informational calls
 - Visit RCE.sequoiaproject.org for FAQs, previous drafts, and other resources
- Become familiar with the contemplated Exchange Purposes and consider how nationwide exchange could support your operations
- Be engaged with stakeholder feedback opportunities

Benefits of TEFCA

- Supports a healthier population through easier access to relevant information
- Establishes a floor for universal interoperability nationwide
- Expands the set of Exchange Purposes beyond a foundation of Treatment
- Simplified information exchange will also support:
 - Medicaid and other state health programs
 - Public health reporting and bidirectional exchange
 - Emergency preparedness and response

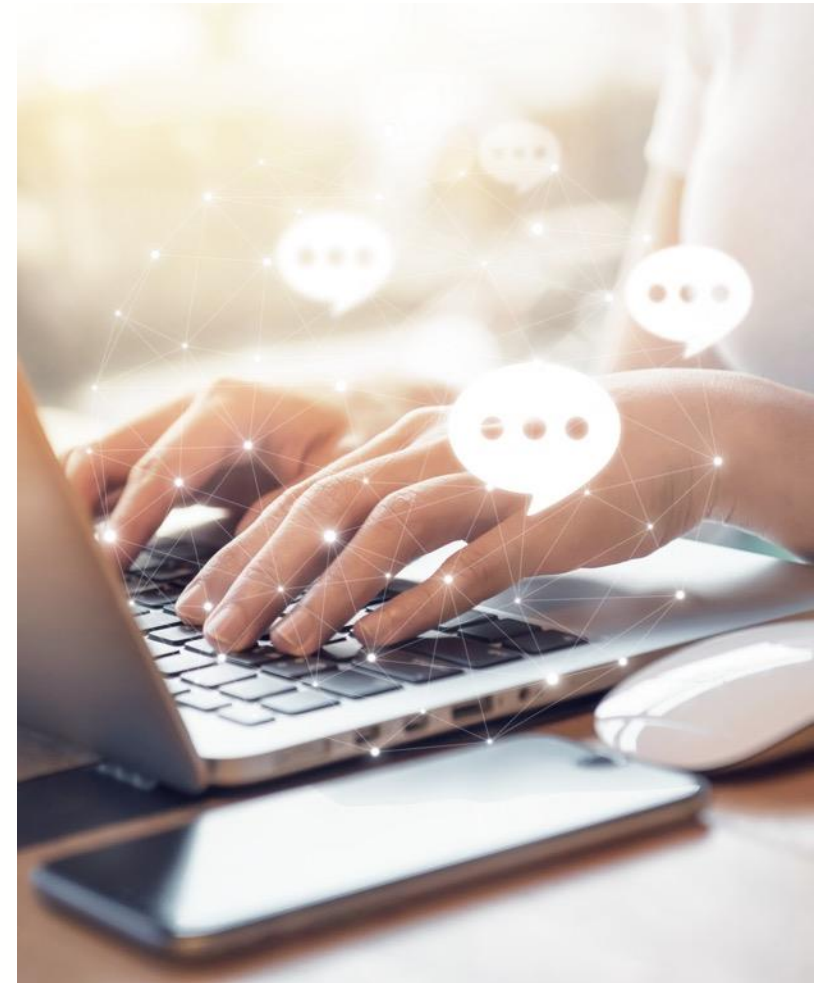
Opportunities for Stakeholder Feedback on Elements of the Common Agreement

Webinar Series:

- Overview; Cooperation and Nondiscrimination; Exchange Purposes and Related Definitions (September 21)
- Deep Dive Topics #1: Permitted Requests, Uses, and Disclosures; Required Responses and Required Information (including Consent); Privacy and Security (September 29)
- Deep Dive Topics #2: QHIN Designation and Eligibility Criteria; Governing Approach; Change Management; Fees; Confidentiality and Accountability (October 5)
- Deep Dive 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/>



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