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January 26, 2022

Overview of the Common Agreement

Mariann Yeager, CEO, The Sequoia Project; RCE Lead
Steve Gravely, Founder and CEO, Gravely Group
Chantal Worzala, Principal, Alazro Consulting

Visit www.RCE.SequoiaProject.org to view the Common Agreement Version 1.



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- TEFCA overview
- What are the components of TEFCA?
- What is in the Common Agreement Version 1?
- What are the Exchange Purposes under TEFCA and how do they work?
- What privacy and security requirements are included in TEFCA?
- How do you become a QHIN?
- How will TEFCA be operationalized?
- Questions & Answers



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TEFCA overview



*“[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]





GOAL 1

Establish a universal policy and technical floor for nationwide interoperability



GOAL 2

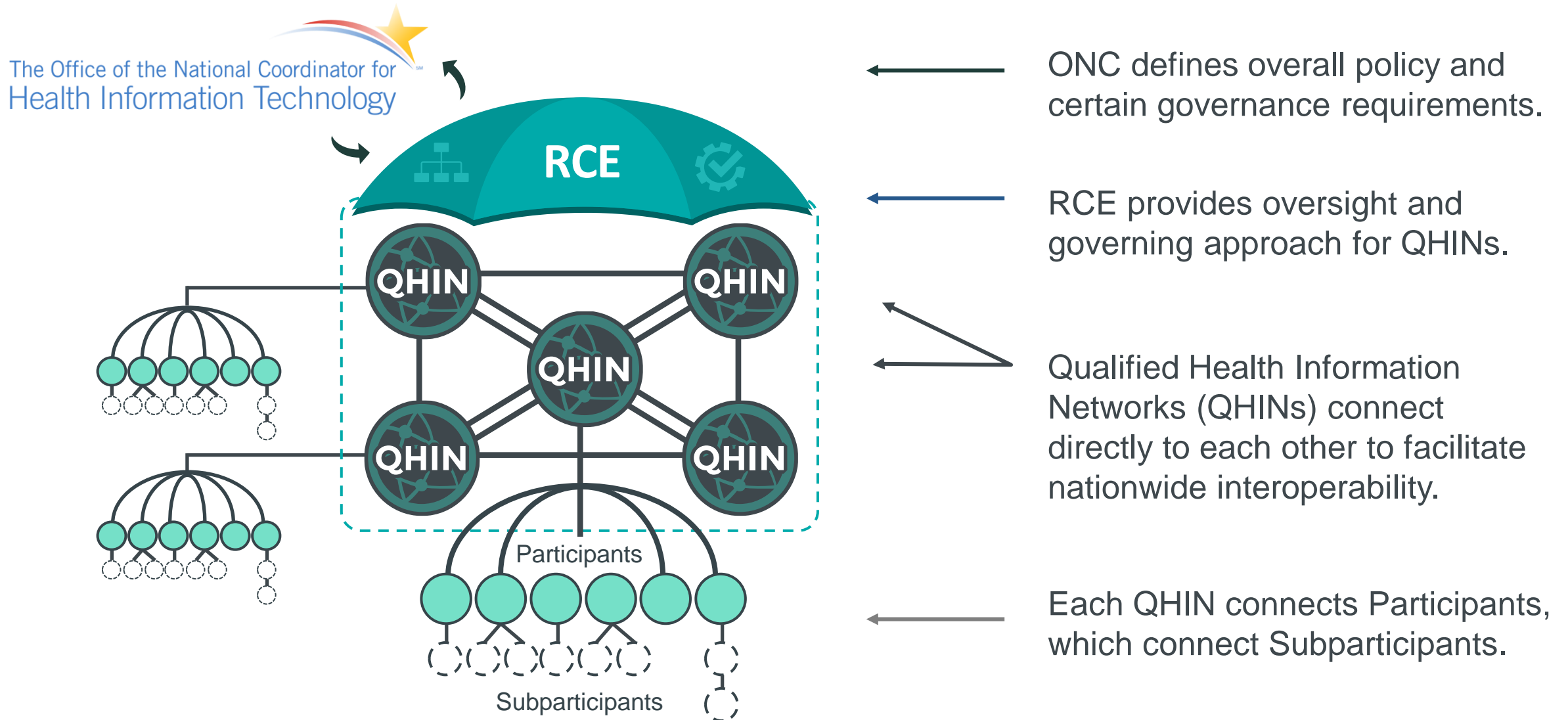
Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value



GOAL 3

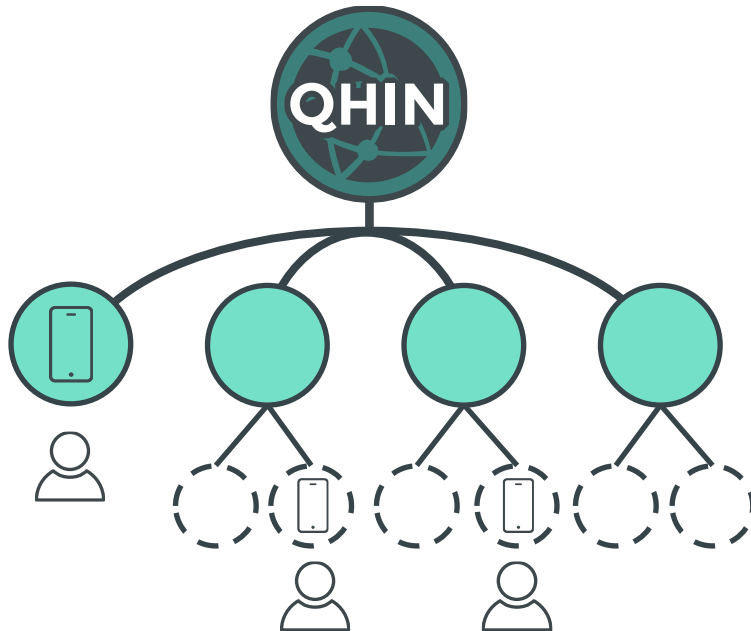
Enable individuals to gather their health care information





How will exchange work under TEFCA?



The Role of a Qualified Health Information Network

QHIN Example



-  Participant
-  Subparticipant
-  Consumer App offered by Participant or Subparticipant
-  Individual

A **QHIN** is an entity with the technical capabilities and organizational attributes to connect health information networks on a nationwide scale.

- High volume
- High reliability
- Abides by the Common Agreement
- Adheres to the QHIN Technical Framework

Participants and Subparticipants will be able to choose their QHIN based on the services provided and fees charged.

Participants and Subparticipants will be able to share information with all other connected entities regardless of which QHIN they choose.

QHINs may not charge fees to other QHINs for any exchange of information under the Common Agreement.

Framework Agreement Flow-Down Provisions



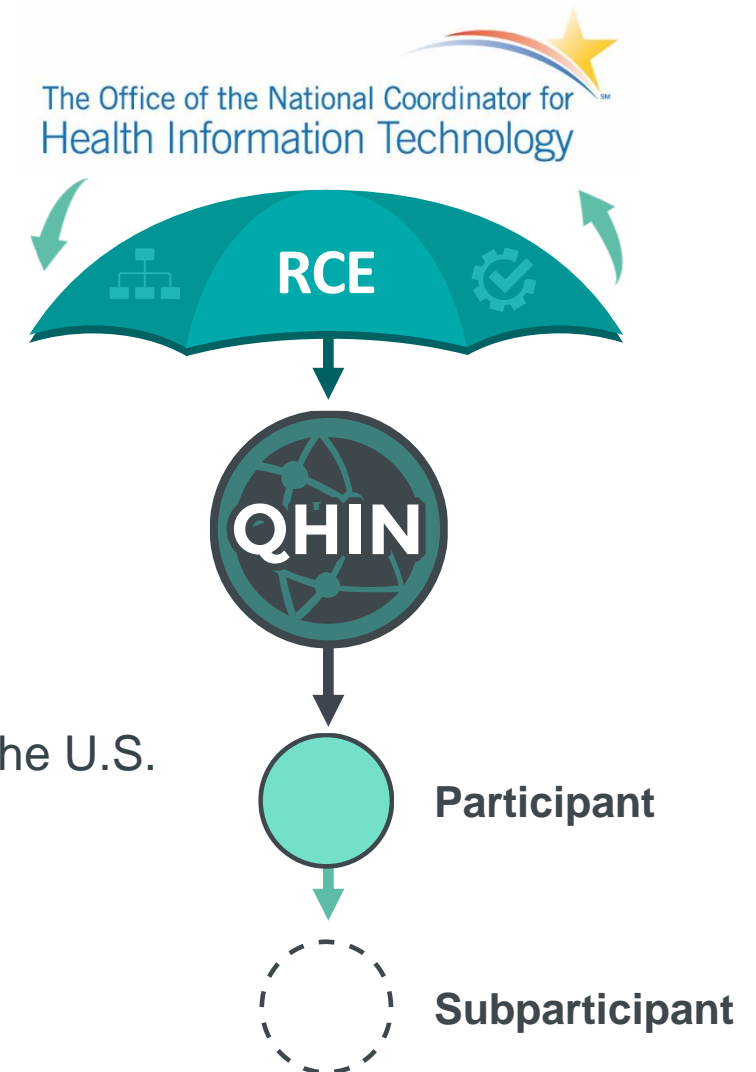
Common Agreement

Each QHIN shall voluntarily enter into a contractual agreement with the RCE by signing the Common Agreement, making all QHINs parties to the Common Agreement. The Common Agreement includes flow-down clauses for the QHIN's agreements with its Participants and each Participant's agreements with its Subparticipants.

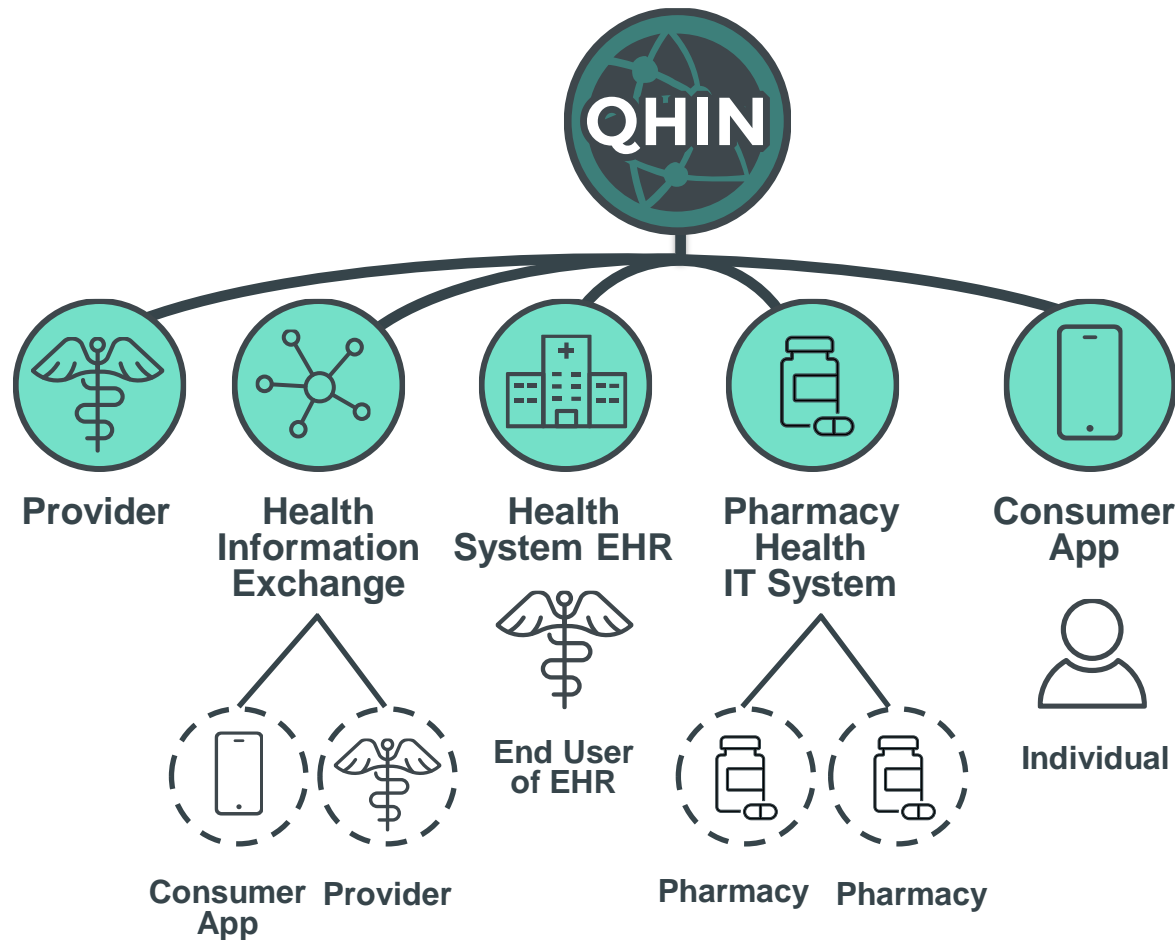
Required Flow-Downs Will Address:

- Cooperation and Nondiscrimination
- Confidentiality
- Utilization of the RCE Directory Service
- Uses, Disclosures, and Responses
- Individual Access Services
- Privacy
- Security
- Special Legal Requirements
- TEFCA Information Outside the U.S.
- Other General Obligations

Entities may connect into exchange at any level, but must abide by the flow-down provisions, which create common “rules of the road.”



Example of QHIN, Participants, and Subparticipants



In this example, the QHIN supports a broad range of different Participants, including a provider, a health information exchange (HIE), an Electronic Health Record (EHR) system, a pharmacy health information technology (IT) system, and a consumer application that is an Individual Access Services (IAS) Provider.

The members of the HIE and the pharmacy health IT system are Subparticipants.

Individuals can connect to QHINs, Participants, and Subparticipants that choose to be IAS Providers. In this example, one consumer app is a Participant of the QHIN and another consumer app is a Subparticipant of the HIE.



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What are the components of TEFCA?



Focus of today's Webinar



Trusted
Exchange
Framework



Common
Agreement



Standard
Operating
Procedures



QHIN
Technical
Framework



QHIN
Onboarding



Metrics



Governing
Approach

The Common Agreement



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- The **Common Agreement** establishes the infrastructure model and governing approach for users in different health information networks to securely share clinical information with each other.
- The Common Agreement is a legal contract that both the RCE signs and a health information network (or other entity) signs.
 - » The latter becomes a Qualified Health Information Network (QHIN) once fully onboarded and designated by the RCE.
- Some provisions of the Common Agreement will flow down to entities in a QHIN's network via other agreements.
- The Common Agreement incorporates the QHIN Technical Framework and the Standard Operating Procedures (SOPs).





The RCE has developed SOPs on topics such as:

- Advisory Groups
- Conflicts of Interest
- Dispute Resolution Process
- Governing Council
- QHIN Security of TEFCA Information
- QHIN Cybersecurity Insurance
- Transitional Council

Additional SOPs will be made available over time.

What is a Standard Operating Procedure? An SOP is a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into this 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. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP. An SOP shall be deemed in effect when adopted pursuant to Section 5.3 of this Common Agreement and listed on a public website.

What is the QHIN Technical Framework?



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The QHIN Technical Framework (QTF) outlines the technical specifications and other technical requirements necessary for QHINs to accomplish exchange.

The QTF primarily addresses QHIN-to-QHIN transactions, and is generally silent on how the necessary functional outcomes are achieved within a QHIN.

There are some requirements that must be enforced at the Participant and Subparticipant level.

The QTF is available at RCE.SequoiaProject.org



Three-Year FHIR Roadmap for TEFCA

- ONC and the RCE have published the [“FHIR® Roadmap for TEFCA Exchange – Version 1.”](#)
- Evolving health IT landscape requires TEFCA to rapidly include approaches that support FHIR.
 - » Approach leverages current state of FHIR today and allows TEFCA policy and technical infrastructure to accelerate FHIR adoption into the future.
 - » In 2022, the RCE will launch working groups to initiate development of the use of FHIR for both QHIN-brokered and facilitated FHIR exchange.

Planned Stages of FHIR Availability in TEFCA:

Stage 1: FHIR Content Support

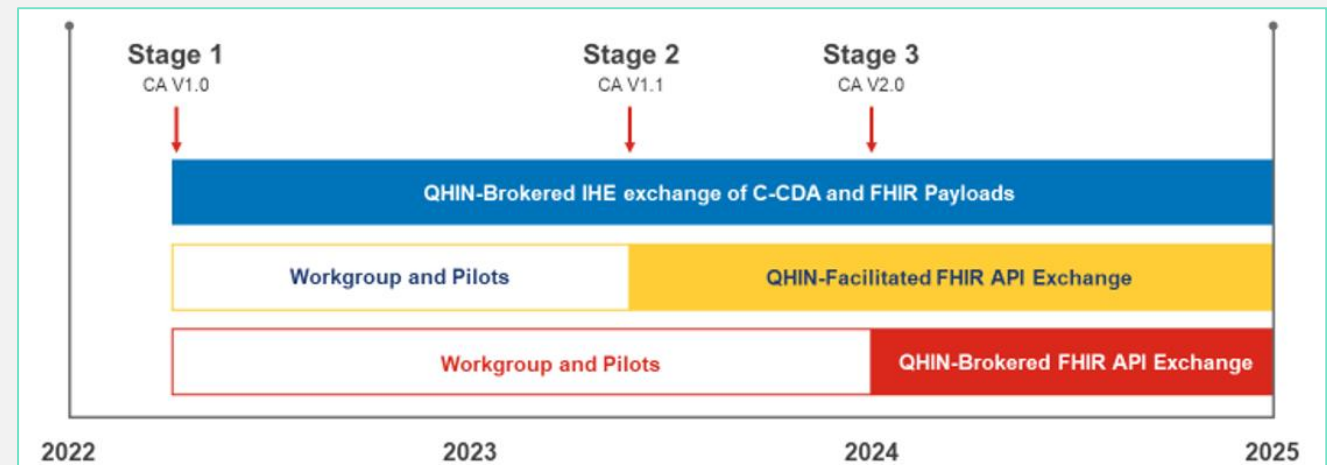
- FHIR exchange possible within QHINs’ own networks
- IHE exchange of FHIR payloads between QHINs *is possible with “out-of-band” coordination.*

Stage 2: Network-Facilitated FHIR Exchange

- QHIN-facilitated FHIR-based exchange available as an *option* under TEFCA.

Stage 3: Network-Brokered FHIR Exchange

- QHIN-facilitated FHIR-based exchange *required* under TEFCA
- QHIN-brokered FHIR API exchange *optionally* available.





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What is in the Common Agreement Version 1?

Sections of the Common Agreement

1. Definitions and Relevant Terminology
2. Incorporation of Recitals
3. Governing Approach
4. QHIN Designation
5. Change Management
6. Cooperation and Non-Discrimination
7. Confidentiality and Accountability
8. RCE Directory
9. TEFCA Exchange Activities
10. Individual Access Services
11. Privacy
12. Security
13. General Obligations
14. Specific QHIN Obligations
15. Dispute Resolution
16. Stability of the QHIN Network
17. Fees
18. Contract Administration



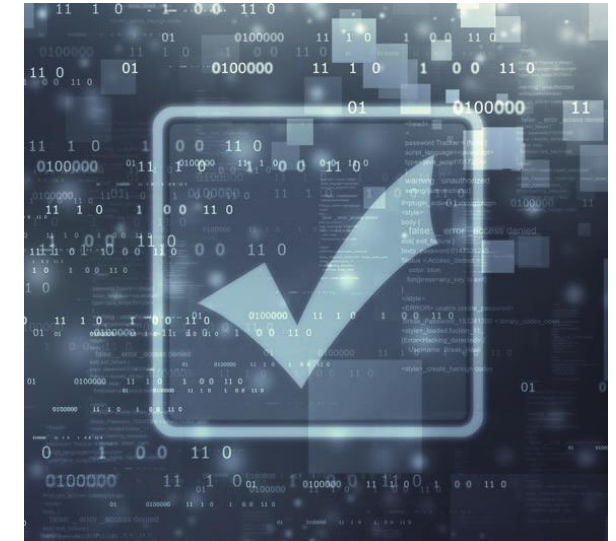
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QHIN Eligibility Criteria, Onboarding, and Designation



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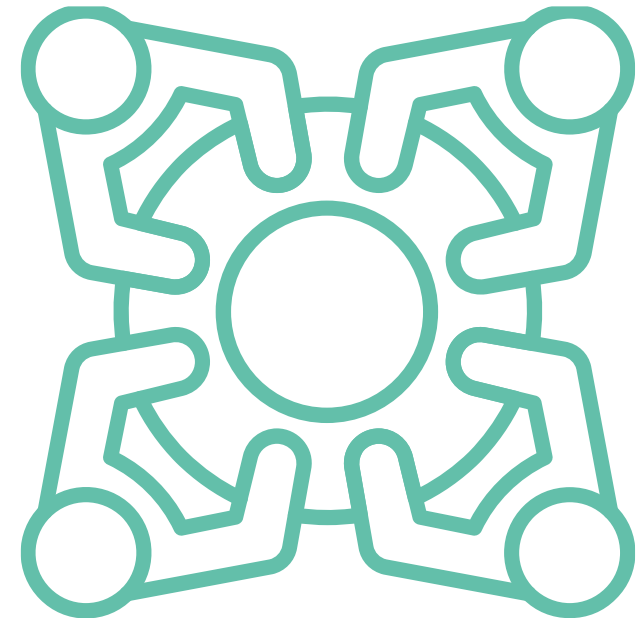
- TEFCA includes QHIN eligibility criteria that generally address:
 - » The ability to perform the required functions of a QHIN, per the QTF.
 - » The legal structure and governing approach for a QHIN.
 - » Demonstrated resources and infrastructure to support a reliable and trusted network.
- QHINs will be expected to provide ongoing reporting on metrics and other information needed to monitor performance over time.
- The RCE will conduct extensive education for candidate QHINs on the application and onboarding processes.
- Only the RCE designates QHINs.



Section 4.1 Eligibility to be Designated. Signatory affirms that it meets the eligibility criteria listed below and the requirements for demonstrating satisfaction of these criteria that are included in the Onboarding & Designation SOP. Signatory must meet the following criteria at the time Signatory submits an application for Designation:

- (i) Signatory must demonstrate that it meets the definition of a U.S. Entity and is not owned or controlled by any non-U.S. person(s) or entity(-ies). The specific, required means to demonstrate this are set forth in an SOP.
- (ii) Signatory is able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate this are set forth in an SOP.
- (iii) Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate Signatory under a provisional status, subject to additional monitoring as further provided in the Onboarding & Designation SOP, including additional review during a provisional period.
- (iv) Signatory must demonstrate that it has in place, at the time of its application to be Designated, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its Health Information Network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this are set forth in an SOP.

- The Common Agreement specifies expectations of QHINs, Participants, and Subparticipants to 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 are prohibited from limiting interoperability with others in a discriminatory manner.





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What are the Exchange Purposes under TEFCA and how do they work?

- The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange.
- Only these six Exchange Purposes are authorized under the Common Agreement.
- A forthcoming SOP will specify that Treatment and Individual Access Services (IAS) require Responses.
- Eventually, the other four Exchange Purposes will require Responses in conformance with forthcoming implementation guides. These will be rolled out with adequate time for stakeholders to prepare.
- Additional Exchange Purposes may be added over time, including whether they require Responses.

Permitted Exchange Purposes



Treatment



Payment



Health Care Operations



Public Health



Government Benefits Determination



Individual Access Services

- “**Treatment**,” “**Payment**,” and “**Health Care Operations**” generally have the same meaning as they have under the HIPAA Privacy Rule and apply to all TEFCA Information, regardless of whether the parties to exchange are HIPAA Covered Entities or Business Associates.
- The **Public Health** Exchange Purpose includes Requests for Uses and Disclosures of information by Public Health Authorities that are consistent with the HIPAA Privacy Rule and other Applicable Law.
- The **Government Benefits Determination** Exchange Purpose supports 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**.



Exchange Purposes - Definitions

- **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 the applicable activities of a Health Care Provider regardless of whether the Health Care 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
- **Government 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 (IAS):** with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, 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 Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

- **TEFCA Requests** will be transmitted via a QHIN-to-QHIN exchange and consistent with the requirements of the Common Agreement.
 - » Only QHINs and certain Participants or Subparticipants can make Requests for each Exchange Purpose.
- **Uses and Disclosures** must adhere to the privacy and security requirements in the Common Agreement, any privacy and security notices, and any requirements of applicable law.



As will be specified in a forthcoming SOP, Requests for Treatment and Individual Access Services are the first types of Exchange Purposes to which TEFCA entities are required to Respond.

Responses would not be required if providing the information is prohibited by Applicable Law or the Common Agreement permits but does not require a Response (see the Common Agreement Section 9.4.1, Exceptions to Required Responses).



The following entities are permitted, but not required, to Respond to Requests:

- Public Health Authorities.
- Users of Government Benefits Determination Exchange Purpose.
- Federal agencies, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law.



A QHIN, Participant, or Subparticipant may only Request information under TEFCA for a specific Exchange Purpose if it is the type of person or entity that is described in the definition of the applicable Exchange Purpose.

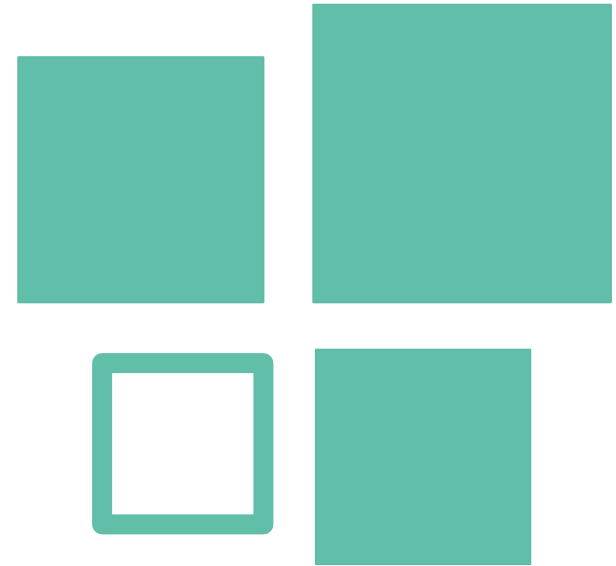
For example, only a Health Care Provider as defined in the HIPAA Rules or the information blocking regulations (or a Business Associate, agent, or contractor acting on that Health Care Provider's behalf) may Request information for the Exchange Purpose of Treatment.

Can Social Services Providers Use Exchange Purposes?



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- A provider of social services that is not a health care provider would generally not be able to request data for Treatment, Payment, or Health Care Operations.
- Such providers of social services could request information if they did so as an Individual Access Services Provider or if they were serving as a contractor to a health care provider, for example.



Individual Access Services (IAS)



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What is IAS?

IAS is, with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, 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 Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

In general, entities are required to Respond to Requests for information for the purpose of Individual Access Services.

What is an IAS Provider?

Each QHIN, Participant, and Subparticipant that offers Individual Access Services.

It is optional to be an IAS Provider.

Individuals will be able to access their own information from all connected entities through an IAS Provider.





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What privacy and security requirements are included in TEFCA?

TEFCA will provide strong privacy protections.

- Most connected entities will likely be HIPAA Covered Entities or Business Associates of Covered Entities, and thus already be required to comply with HIPAA privacy and security requirements.
 - » **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. As a matter of general policy, once TEFCA Information (TI) is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.
- The Common Agreement requires each Non-HIPAA Entity to protect individually identifiable information that it reasonably believes is TEFCA Information in substantially the same manner as HIPAA Covered Entities protect Protected Health Information (PHI), including most provisions of the HIPAA Privacy Rule.
 - » This includes, for example, Health Care Providers and IAS Providers that are non-HIPAA Entities.
 - » IAS Providers have additional requirements (see later slides).





TEFCA will provide strong security protections.

- QHINs will be expected to meet a high bar for security, including:
 - » Third-party certification to industry-recognized cybersecurity standards, in addition to complying with the HIPAA Security Rule.
 - » Annual security assessments.
 - » Have a Chief Information Security Officer.
 - » Have cyber risk coverage.
- Flow-down contract provisions for all Participants and Subparticipants:
 - » Non-HIPAA Entities (NHEs) must comply with the HIPAA Security Rule with respect to all individually identifiable information that the entity reasonably believes is TEFCA Information.
- Notice of TEFCA Security Incidents involving or affecting exchange:
 - Are required of QHINs, Participants and Subparticipants.
 - Generally designed to avoid conflict with Applicable Law and duplicative notification requirements.
- All TEFCA entities shall evaluate the risks of any Uses and/or Disclosures of TEFCA Information outside the U.S to evaluate whether they satisfy the HIPAA Security Rule.
- The RCE will actively facilitate security activities, with the support of a Cybersecurity Council drawn from participating QHINs.



TEFCA Security Incident - Definition



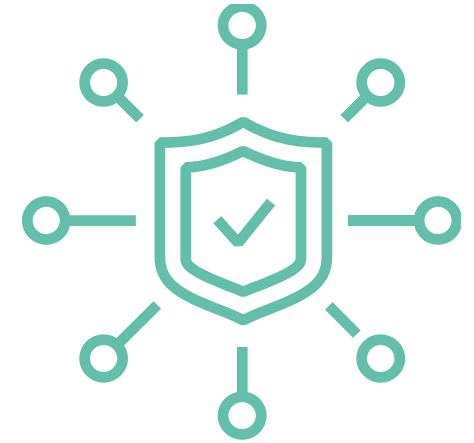
TEFCA Security Incident(s):

- (i) An unauthorized acquisition, access, Disclosure, or Use of unencrypted TEFCA Information in transit using the Connectivity Services or pursuant to any Framework Agreement between Signatory and its Participants, between Signatory's Participants and their Subparticipants, or between Subparticipants, but NOT including the following:
 - (a) Any unintentional acquisition, access, or Use of TEFCA Information by a workforce member or person acting under the authority of a QHIN, Participant, or Subparticipant, if such acquisition, access, or Use was made in good faith and within the scope of authority and does not result in further Use or Disclosure in a manner not permitted under Applicable Law and this Common Agreement.
 - (b) Any inadvertent Disclosure by a person who is authorized to access TEFCA Information at a QHIN, Participant, or Subparticipant to another person authorized to access TEFCA Information at the same QHIN, Participant, or Subparticipant, or Organized Health Care Arrangement in which a QHIN, Participant, or Subparticipant participates or serves as a Business Associate, and the information received as a result of such Disclosure is not further Used or Disclosed in a manner not permitted under Applicable Law and this Common Agreement.
 - (c) A Disclosure of TEFCA Information where a QHIN, Participant, or Subparticipant has a good faith belief that an unauthorized person to whom the Disclosure was made would not reasonably have been able to retain such information.
 - (d) A Disclosure of TEFCA Information that has been de-identified in accordance with the standard at 45 CFR § 164.514(a).
- (ii) Other security events (e.g., ransomware attacks), as set forth in an SOP, that prevent the affected QHIN, Participant, or Subparticipant from responding to requests for information as required under this Common Agreement or otherwise adversely affect their participation in QHIN-to-QHIN exchange.



TEFCA IAS Providers must, among other requirements:

- Have a written privacy and security notice.
- Obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed.
- Provide Individuals with the right to delete their information, with certain exceptions.
- Provide Individuals with the right to obtain an export of their data in a computable format.
- Take the following steps with respect to all individually identifiable information they hold:
 - » Protect such information in accordance with all TEFCA security requirements.
 - » Encrypt all information.





- IAS Providers will need to implement security requirements, including encryption and certain security incident notifications.
- These requirements are in addition to the requirement of abiding by the HIPAA Security Rule.



- Individual Access Services (IAS) Providers are required to obtain express consent from Individuals.
- TEFCA places no consent requirements on other Participants beyond what is required by applicable law, such as HIPAA.
 - » 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.
 - » Where HIPAA or other applicable laws require patient authorization or consent, it is also required for TEFCA exchange.
- The QTF includes a mechanism for QHINs, Participants, and Subparticipants to share such electronic consent documents with each other.

Applicable Law and Order of Precedence



- TEFCA will function within the constraints of Applicable Law, including state, local, tribal, and federal law.
- If there is a conflict between Applicable Law and provisions of the Common Agreement, the order of precedence is as follows:
 - i. Applicable Law;
 - ii. The Common Agreement including the Required Flow-Down provisions to be included in the agreements between TEFCA Entities;
 - iii. The QHIN Technical Framework (QTF);
 - iv. The Dispute Resolution Process, as set forth in the Common Agreement and an SOP;
 - v. All other SOPs; and
 - vi. All other attachments, exhibits, and artifacts incorporated into the Common Agreement by reference; and
 - vii. Other RCE plans, documents, or materials made available regarding activities conducted under the Framework Agreements.
- An entity **Disclosing** data must follow the Applicable Law that applies to it for disclosing data.
- An entity **Requesting** data must follow the Applicable Law that applies to it for the actions it takes in making Requests.



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How do you become a QHIN?



The RCE will support prospective QHINs:

- ☐ Educational opportunities
- ☐ Eligibility criteria in the Common Agreement
- ☐ Application
- ☐ QHIN Onboarding & Designation SOP
- ☐ Designated Point of Contact



For more information on the QHIN application process, visit: www.RCE.SequoiaProject.org.

QHIN Application Process

Pre-application Activities



Prospective QHIN reviews the Common Agreement, QTF, and SOPs.

Prospective QHIN participates in educational sessions.



Prospective QHIN signs the Common Agreement and submits QHIN Application package.

The RCE makes an eligibility determination.

QHIN onboarding



If application is accepted, prospective QHIN begins the QHIN onboarding process, including technical testing and production connectivity validation.



If all requirements are met, RCE counter-signs the Common Agreement and designates the applicant as a QHIN.



RCE provides written notice of QHIN Designation to both the applicant and ONC.

All relevant materials and resources will be available at www.RCE.SequoiaProject.org.



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How will TEFCA be operationalized?

Timeline to Operationalize TEFCA

2021

- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q2 of 2022

- QHINs begin signing Common Agreement and applying for designation

2023

- Establish Governing Council
- Follow change management process to iterate Common Agreement, SOPs, and QTF, including to support FHIR-based exchange



Q1 of 2022

- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q3 and Q4 of 2022

- Onboarding of initial QHINs
- Additional QHIN applications processed
- RCE establishes Transitional Council
- RCE begins designating QHINs to share data
- Prepare for TEFCA FHIR exchange pilots

Resources

- Common Agreement v. 1
- QHIN Technical Framework
- FHIR® Roadmap for TEFCA
- Standard Operating Procedures
- User's Guide
- Benefits of TEFCA by Stakeholder Factsheets
- FAQs

<https://rce.sequoiaproject.org/tefca-and-rce-resources/>

Additional Resources:

<https://www.healthit.gov/tefca>

Events

- 1/26: Common Agreement Overview Webinar
- 2/2: QHIN Technical Framework (QTF) & FHIR® Roadmap Webinar
- 2/3: Common Agreement & Standard Operating Procedures (SOPs) Webinar
- 3/8: TEFCA Panel at ViVE
- 3/14: Morning Keynote at HIMSS Pre-Conference Symposium
- 3/15: TEFCA Education Session at HIMSS

<https://rce.sequoiaproject.org/community-engagement/>



Questions & Answers



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