

Elements of the Common Agreement: Questions & Answers

October 19, 2021

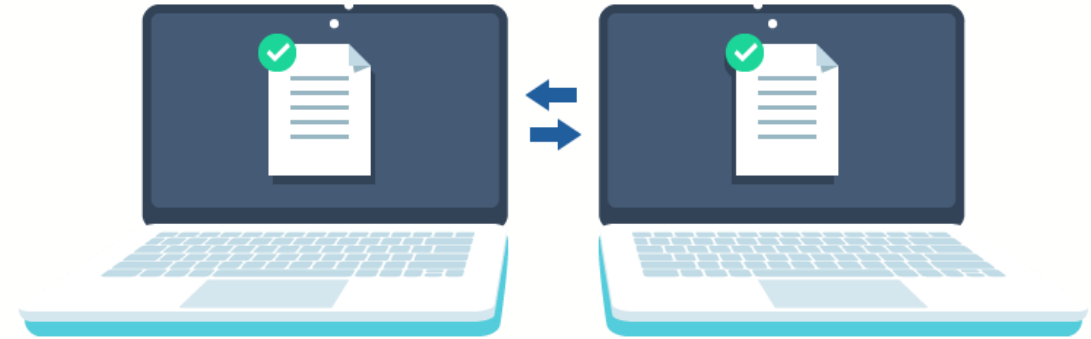


ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

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 and Brief Overview
- Highlight QTF Stakeholder Feedback
- Common Agreement Questions and Answers



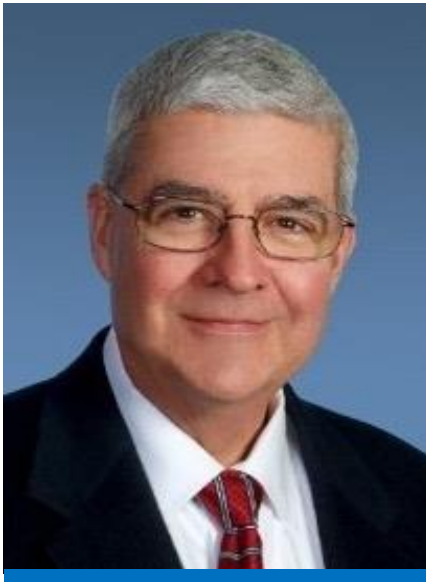
Meet the RCE Team



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

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

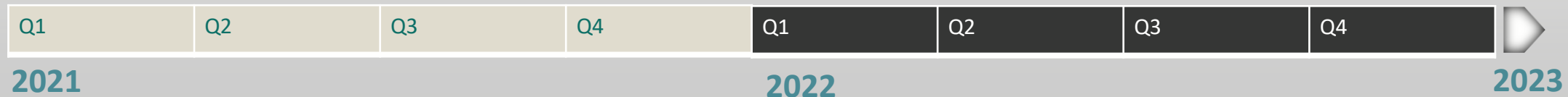
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

Calendar Q1 of 2022

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

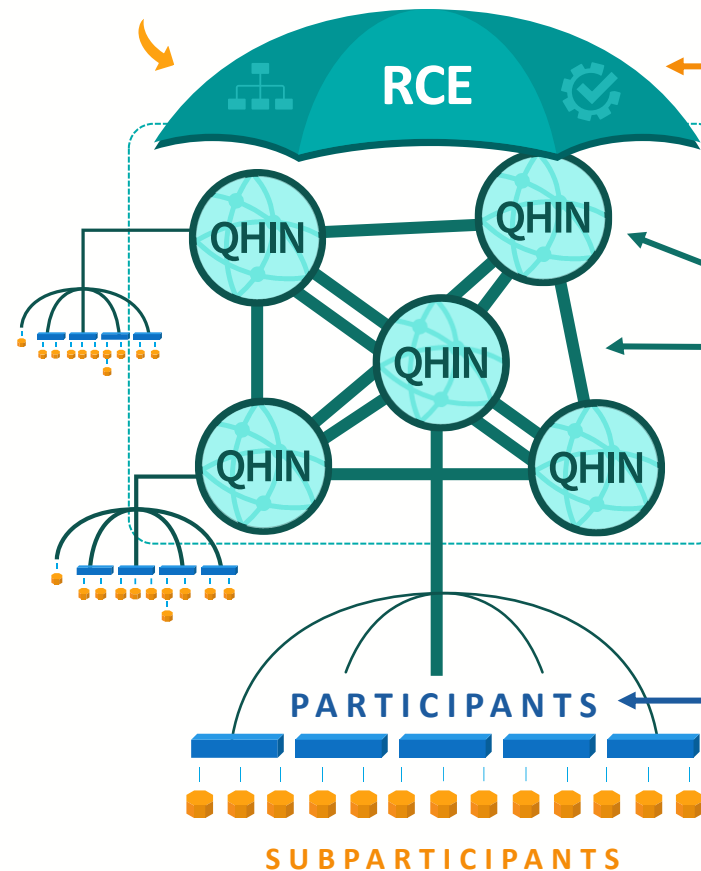
During 2022

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



How Will TEFCA Work?

The Office of the National Coordinator for
Health Information Technology



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.

The Value Proposition for TEFCA



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The Nationwide Network Based on the Common Agreement

Benefits for the Payer Community

Together with the Office of the National Coordinator for Health Information Technology (ONC), the Trusted Exchange Framework and Common Agreement (TEFCA) as required by the 21st Century Cures Act, operational, the network-of-networks based on the Common Agreement will facilitate exchange of health information on a nationwide scale, simplify connectivity among networks, and create efficiency by establishing a standardized approach to exchange policies and technical frameworks. Together with ONC, we announced in July 2021 that we plan to publish the Common Agreement V1 in Q1 of 2022.

The network based on the Common Agreement will offer a nationwide approach for the exchange of health information to support a range of exchange purposes, enabling a multitude of use cases.

The Common Agreement's single set of rules will simplify connectivity to a health information network of patients and health plans. Consistent policies and technical approaches will increase the overall exchange of health information.

The ultimate goal of the network based on the Common Agreement is to establish a floor of uniformity across the country. This will enhance provider, payer and consumer access to health information for clinical decision-making, improved outcomes, and lower costs.



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The Nationwide Network Based on the Common Agreement

Benefits for State Governments and Public Health

Together with the Office of the National Coordinator for Health Information Technology (ONC), we are developing the Trusted Exchange Framework and Common Agreement (TEFCA) as required by the 21st Century Cures Act. Once operational, the network-of-networks based on the Common Agreement will facilitate exchange of health information on a nationwide scale, simplify connectivity among networks, and create efficiency by establishing a standardized approach to exchange policies and technical frameworks. Together with the ONC, we announced in July 2021 that we plan to publish the Common Agreement V1 in Q1 of 2022.

The network based on the Common Agreement will offer a nationwide approach for the exchange of health information to support a range of exchange purposes, enabling a multitude of use cases.

The Common Agreement's rules will reduce the burden health information networks (HINs) and their participants currently face when they establish connections with entities outside their networks. Consistent policies and technical approaches will also increase the overall exchange of health information. For example, in the area of public health, use cases could include electronic case reporting, immunization registry data sharing, or case investigation.



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The Nationwide Network Based on the Common Agreement

Benefits for Health Care Providers Across the Continuum

Together with the Office of the National Coordinator for Health Information Technology (ONC), we are developing the Trusted Exchange Framework and Common Agreement (TEFCA) as required by the 21st Century Cures Act. Once operational, the network-of-networks based on the Common Agreement will facilitate exchange of health information on a nationwide scale, simplify connectivity among networks, and create efficiency by establishing a standardized approach to exchange policies and technical frameworks. Together with ONC, we announced in July 2021 that we plan to publish the Common Agreement V1 in Q1 of 2022.

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The Common Agreement's single set of rules will simplify connectivity to a health information network of patients and health plans. Consistent policies and technical approaches will increase the overall exchange of health information.

The overall goal of TEFCA is to establish a floor of uniformity across the country. This will enhance provider, payer and consumer access to health information for clinical decision-making, improved outcomes, and lower costs.



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The Network Based on the Common Agreement

Benefits for Health Information Networks (HINs)

Together with the Office of the National Coordinator for Health Information Technology (ONC), we are building the Trusted Exchange Framework and Common Agreement (TEFCA) established by the 21st Century Cures Act. Once operational, the network based on the Common Agreement will facilitate exchange of health information on a nationwide scale, simplify connectivity among networks, and create efficiency by establishing a standardized approach to exchange policies and technical frameworks.

The network based on the Common Agreement will offer a nationwide approach for the exchange of relevant health information to support a range of exchange purposes, such as treatment, payment, quality assessment, benefits determination, consumer access to health information, and public health.

The network based on the Common Agreement will provide a common set of rules that are federally recognized, greatly reducing the burden health information networks (HINs) currently face when they try to establish connections with entities outside their networks. Consistent policies and technical approaches will increase the overall exchange of health information. The network based on the Common Agreement will also provide a structure for engaged parties to work together on coordinated, uniform adoption of new technologies and use cases over time.

The ultimate goal of the network based on the Common Agreement is to enhance provider and consumer access to health information that supports better clinical decision-making, improved outcomes, and lower costs. HINs participating in the network based on the Common Agreement will play a pivotal role in reaching that goal and will benefit greatly from its achievement.



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The Nationwide Network Based on the Common Agreement

Benefits for Patients and Consumers

We live in a digital world. Increasingly, patients and consumers expect health care to be digital too. They want to be able to access, control and share their health information electronically. Moreover, many consumers want to bring together all of their health information – not just the data held by a single doctor or hospital. For example, many want to see their test results or immunization records over time or share their health history with a new doctor after moving or changing health insurance. All of this needs to happen in a secure and protected way.

We are working with the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC) to make it so that your health information can be shared easily and securely with you, your doctors, and those who support you on your health journey. This, in turn will support better care and lower health care costs.

We are doing this by setting a common set of rules on technical standards, privacy requirements and related policies for health information networks. These policies will be laid out in the Trusted Exchange Framework and the Common Agreement (TEFCA). By setting technical and other rules on how data can be accessed and securely shared, this network-of-networks approach will make it possible for data to flow more seamlessly to support your health and care.

TEFCA Components



Common
Agreement



Standard
Operating
Procedures



QHIN
Technical
Framework



QHIN
Onboarding



Metrics



Governing
Approach

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

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.

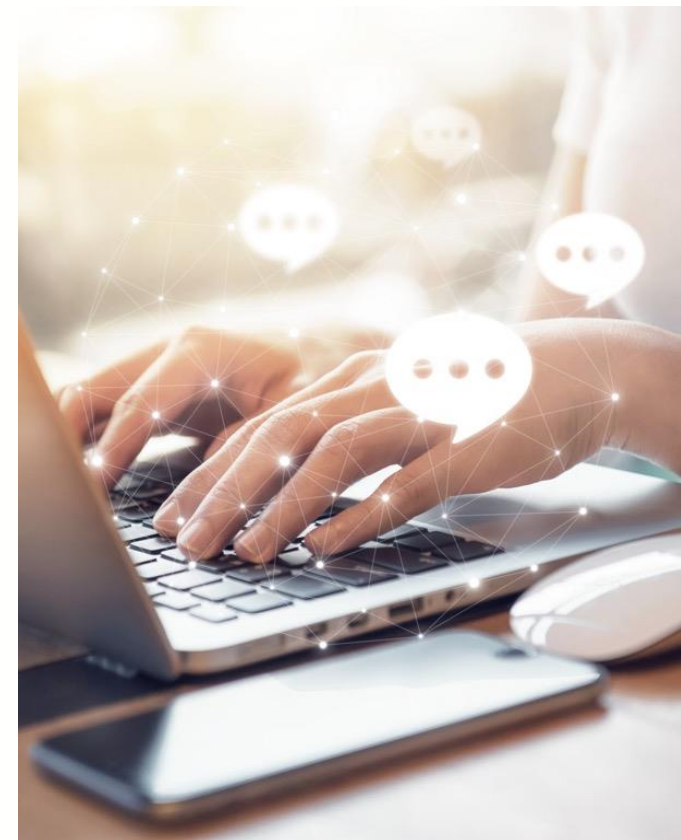
Opportunities for Stakeholder Feedback on Elements of the Common Agreement

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.**

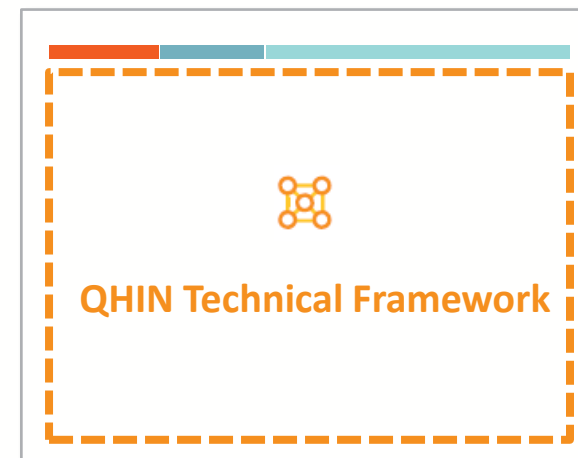
QHIN Technical Framework

What is the QHIN Technical Framework?

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

The QTF primarily addresses QHIN-to-QHIN transactions, and where possible we propose to be silent on how the necessary functional outcomes are achieved within a QHIN.

Nonetheless, there are some requirements that must be enforced at the Participant and Subparticipant level.



**Draft published by the RCE
for public feedback until 9/17**

<https://rce.sequoiaproject.org/qhin-technical-framework-feedback/>

Elements of the QHIN Technical Framework

Supported Information Flows:

- Patient Discovery
- Document Query
- Message Delivery

Functions and Technology to Support Exchange

- Certificate Policy
- Secure Channel
- Mutual QHIN Server Authentication
- User Authentication
- Authorization and Exchange Purpose
- Patient Identity Resolution
- Individual Privacy Preferences
- Directory Services
- Auditing
- Error Handling
- Onboarding and Testing

Approach:

- Build from current capabilities
- Deploy known standards
- Keep an eye toward future approaches



Questions & Answers

Common Agreement Elements

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 Associates 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 Provider 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



What privacy expectations should TEFCA have for other non-HIPAA entities?

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

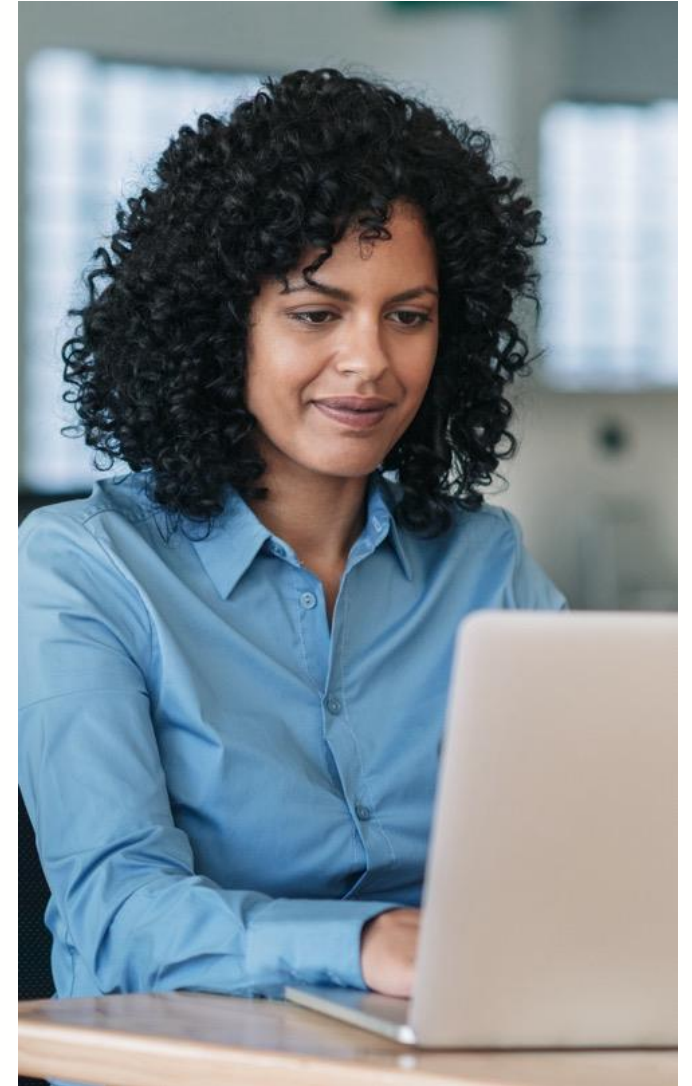
TEFCA will promote strong security protections.

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.

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.



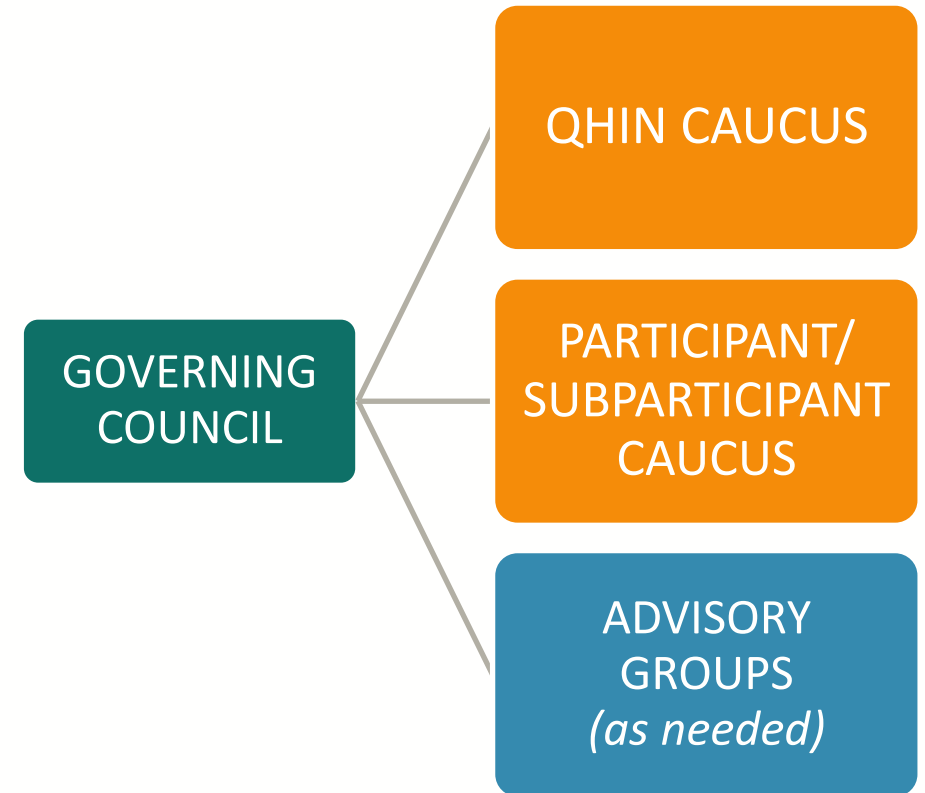
IAS Privacy and Security Requirements (2)

- 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

1. 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.

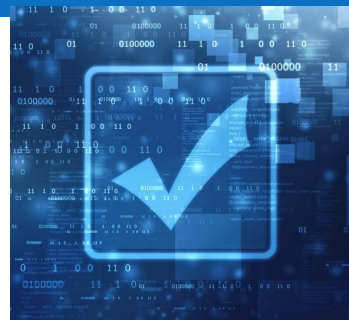
QHIN Eligibility Requirements

QHIN Designation and Eligibility Criteria - Overview

- Only the RCE would be able to designate a QHIN
- Application, assessment, testing and on-boarding processes are under development
- QHINs will be expected to provide ongoing reporting on metrics and other information needed to monitor performance over time
- The Common Agreement would include specific QHIN eligibility criteria that generally address:
 - The ability to perform all of the required functions of a QHIN, as identified in the QTF;
 - The legal structure and governing approach for the QHIN; and
 - Demonstrated resources and infrastructure necessary to support a reliable and trusted network.



QHIN Designation and Eligibility Criteria – U.S. Entity



1. Signatory must demonstrate that it meets the definition of U.S. Entity.

- Provide a copy of charter, principal place of business, certificate of good standing, organizing documents, and list of current officers and members of governing body/bodies.
- Foreign ownership considerations

QHIN Designation and Eligibility Criteria – Exchange Capabilities



2. Signatory is able to exchange Required Information, as defined in this Common Agreement.

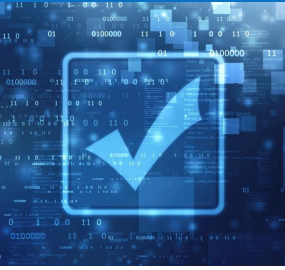
- Be capable of the exchange of Required Information for all Exchange Purposes.
- Describe the exchange purposes that are permitted on its network;
- Be capable of conducting exchange with unaffiliated organizations. Signatory must describe entities participating in its network, including their affiliation or non-affiliation with one another
- Describe how it currently facilitates exchange of health information (e.g. query, push, other exchange modality), and length of time with this experience
- Submit data on number and type of organizations that utilize its exchange services and whether it limits participation or is specialized in any manner
- Submit copies of data sharing agreements, operating policies and procedures, and other legal agreements and related documents that govern the operation of its health information network.

QHIN Designation and Eligibility Criteria – Required Functions and Provisional QHINs



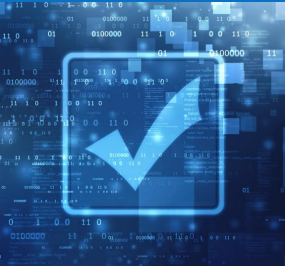
3. **Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.** Signatory can demonstrate this by having been in operation and supporting the 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 as a QHIN. 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 the Signatory as a provisional QHIN** as further provided in the QHIN Designation SOP, including additional review during a provisional period and the potential to have the provisional status removed if Signatory achieves a predetermined level of technical competency.

QHIN Designation and Eligibility Criteria – Required Functions



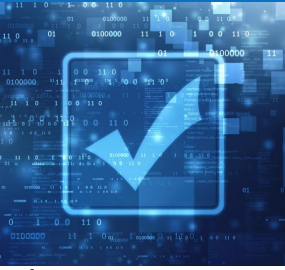
- Demonstrated ability to successfully process a high number of transactions through a high performing, reliable environment – tens of millions of transactions each day. Provide:
 - Average monthly transaction volumes
 - Average annual transaction volumes.
- Provide specific information regarding its architecture and an attestation of its ability to expand the volume of data transactions through its network. This information shall include the ability to add technology capacity, staff, and other needed resources. Signatory must provide specific evidence of having been in operation and supporting the query functionality as outlined in the QTF for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN. RCE can also consider other evidence.
- Signatory must identify any gaps between its current technical infrastructure and the requirements of the QTF and identify its plan to address these gaps so that Signatory will be able to fully comply with the QTF once Signatory is Designated as a QHIN.

QHIN Designation and Eligibility Criteria – Provisional QHINs



- The RCE can designate Signatory as a QHIN, assuming Signatory satisfies all other requirements, on a provisional basis if the RCE determines that Signatory can reasonably support the query functionality as outlined in the QTF for a specified period of time in production, exchange with other QHINs and otherwise complies with the requirements of the Common Agreement. The RCE will consider the following when making this determination:
 - Evidence to show that Signatory has been engaged in the transmission of Required Information using a different but functionally comparable exchange method to the QTF in a live production environment for at least twelve (12) consecutive months during the twelve (12) months immediately preceding its application to the RCE.

QHIN Designation and Eligibility Criteria – Provisional QHINs



- A “Provisional QHIN” is an organization that the RCE Designates as a QHIN on a provisional basis (“Provisional Status”) based on a determination that the organization: (1) does not, at the time of its application, satisfy all of the eligibility criteria, but (2) demonstrates the likelihood of being able to satisfy all such criteria during the course of the Provisional Status. The Provisional Status is a 12-month period in which a Provisional QHIN has the opportunity to demonstrate the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs.
- The RCE may impose such limitations on Signatory during its Provisional Status as the RCE deems reasonably necessary to allow the RCE to monitor Signatory’s performance. This may include, but is not limited to, requiring Signatory to provide information about the type and volume of exchange activity, any problems that Signatory or its Participants or Subparticipants experience with exchange activity, participation in meetings with the RCE to discuss Signatory’s performance during the Provisional Status, and any other matters that the RCE determines to be necessary. The Provisional Status shall continue for a time period of twelve (12) months following the RCE Designating Signatory as a Provisional QHIN; provided, however, that the RCE has the right to suspend (and toll) or terminate Signatory’s Provisional Status at any point if the RCE determines that Signatory is in non-compliance with the requirements and obligations that are applicable to Provisional QHINs, as more fully set forth in the applicable SOP.

QHIN Organizational Infrastructure, Legal Authority, and Functional and Technical Ability



4. Signatory must demonstrate that it has in place, at the time of its application to be Designated as a QHIN, the organizational infrastructure and legal authority to comply with the obligations of the Common information 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.
 - Network governance
 - Financial and personnel resources
 - Security, including certification under a nationally recognized security framework and CISO
 - Detailed information about any HIPAA reportable breaches of ePHI over the past three years
5. Signatory has the functional and technical ability to comply with the QHIN Technical Framework.
 - Signatory must provide evidence of compliance with the QHIN Technical Framework, including but not limited to any required conformance, interoperability, or partner testing as specified in the *RCE QHIN Testing and Onboarding Process*.



Cybersecurity Insurance

Signatory shall provide evidence of one of the following:

- (1) a certificate of insurance demonstrating that Signatory has current cyber-liability coverage that meets the requirements set forth in the applicable SOP;
- (2) that Signatory has applied for cyber-liability coverage that meets the requirements set forth in the applicable SOP, including an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or
- (3) available internal funds, separate from those attested to in 4(c)(i), to self-insure against a cyber-incident up to the amount required by the applicable SOP.