

The Sequoia Project, who is the entity operationalizing the national framework for health information exchange called TEFCA (the Trusted Exchange Framework and Common Agreement), has recently released information how entities can participate under the framework.

What happened?

Through two new Standard Operating Procedures (SOPs) and a Qualified Health Information Network (QHIN) application, organizations are now able to determine how they will fit in this national framework to begin sharing information across state lines. One of the SOPs titled, [Draft QHIN Onboarding and Designation Standard Operating Procedure \(SOP\)](#) and the corresponding [Draft QHIN Application](#) outline the stringent legal, technical, and administrative requirements for entities hoping to facilitate the national exchange on behalf of Participants and Subparticipants. The remaining SOP titled [Draft Types of Entities That Can Be a Participant or Subparticipant in TEFCA SOP](#) defines which entities will qualify as a Participant or Subparticipant under the framework. These entities will not be responsible for exchange themselves, but will instead connect to a QHIN, who will facilitate exchange for them.

Why does it matter?

USQHIN has been closely monitoring the release of TEFCA and its relative components—including, the legal Common Agreement, QHIN Technical Framework, and SOPs—and plans to submit an application for QHIN status. While the previous documents have touched on what would be required of QHINs from high level, these recent drafts provide the checklist of requirements and evidence necessary to demonstrate an entity can exchange information on the caliber necessary under the framework. Over the next several months, USQHIN will align its mission of rationalizing interstate data exchange at national scale with the framework and gather the appropriate evidence necessary for a successful application.

Please reach out to us at help@USQHIN.org for more information.

Draft QHIN Onboarding and Designation SOP

Main Takeaway: None of the information in the SOP is surprising or new, but it does go into much more detail on the “checklist” the QHIN must complete in the application process. The testing section at the bottom would be the most useful for our internal teams to determine what must be done to satisfy the query testing. Including Jason for that reason.

- Section 4 of the Common Agreement
- States application process and evidence for becoming QHIN
- Eligibility
 - Must be a US Entity
 - Copy of Charter

- Certificate of good standing
- Articles of Incorporation, Bylaws
- Current officers
- Able to exchange Required Information
 - Describe exchange purposes
 - Describe use of query, push, etc
 - Length of time for each functionality
 - Number and type of orgs participating in network
 - Data sharing agreement
- Demonstrate compliance with CA, QTF, SOPs
 - Query for at least 1 year (can be provisional QHIN if less)
 - High transaction functionality (in the millions)
 - Monthly, annual transaction volumes
 - Ability to expand volume of transactions
 - Provisional status
 - Does not satisfy all criterion
 - Likely to demonstrate all criterion
 - Cannot exceed 1 year itself
 - Limitations during this time
- Organizational structure and legal authority
 - Governance
 - Oversight of technical framework
 - Legal means to enforce
 - Formal structure
 - Cooperation and dispute resolution
 - Breach process
 - Sanction process
 - Change process
 - Participants participation codified, enforced, communicated
 - Financial and personnel resources
 - Minimum cash or borrowing arrangements
 - Describe organization and personnel to support
 - Cyber liability insurance
 - Security
 - Certified by national framework
 - CISO must have executive level responsibility
- Application Process
 - Submit communication of intent to apply
 - Onboarding SOP
 - Common Agreement
 - QHIN Application
 - RCE will review application

- 30 day to remediate issues
- Review of complete application
 - 60 days to review
 - 10 days to remediate issues/ answer questions
 - Can withdraw application and pick up within six months
 - Deny application- can reapply in six months or appeal
 - Governing and Transactional Council will decide merits of appeal but RCE and ONC decides within 70 days
- Assertion of Compliance
 - Technical testing in line with QTF
 - QHIN onboarding
 - Onboarding process
 - Regular check ins
 - Testing overview
 - Connect to other QHINs
 - Conformance Testing
 - Non Production Partner Testing
 - Production Connectivity Validation
 - Timeline
 - Pre-production
 - Within 1 year of approval
 - Conformance
 - Sequoia Interoperability Testing Platform (ITP)
 - Submit application testing package with configuration information and information on users to need to have accounts
 - Non production partner testing
 - Each QHIN will complete non production tests against test instances of QHIN gateway (Test Ecosystem)
 - Successfully complete transactions
 - Query
 - Match patient, return at least one document and retrieve
 - 100% success required
 - RCE Directory Read/ Write API key
 - ONLY synthetic data, no clinical data
 - For first cohort, just demonstrate with 1 other QHIN, for later cohorts, demonstrate with many
- Designation and Post Production Testing
 - Designated QHIN status
 - QHIN configures production system for connectivity

- Initiate patient discovery to all other QHINs and receive no matching found for all transaction
- Must all complete testing with production validation partner
 - To demonstrate connectivity can be established
- In one month, QHIN must have successful transaction with all other in production QHINs
 - Sanctions if not

Standard Operating Procedure (SOP): Types of Entities That Can Be a Participant or Subparticipant in TECA

Main Takeaway: This defines who may be able to exchange information or submit requests to QHINs. The most interesting portion is the written list they have come up with thus far. I have highlighted below

- Differentiation
 - QHIN, Participant or Subparticipant can only exchange information under the network if they are the TYPE of Participant or Subparticipant that can request information for that Exchange PURPOSE.
 - E.g. only provider (or their Business Associate) can request information for exchange purpose of Treatment
 - These determinations of what TYPE of Participant or Subparticipant can request information under each Exchange Purpose will be outlined in the Common Agreement
 - **This SOP will discuss what a Participant or Subparticipant is or who qualifies to become one**
- Definitions
 - Participant: to the extent permitted by applicable SOP(s), a U.S. Entity 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 information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.
 - Subparticipant: to the extent permitted by applicable SOP(s), a U.S. Entity 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 as described in Section 9 of this Common Agreement to send and/or receive information; or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used as described in Section 9 of this Common Agreement to send and/or receive information.
- **Entities that can be a Participant or Subparticipant**
 - A Covered Entity or its Business Associate
 - A Government Health Care Entity or its agent or subcontractor

- A Health Care Provider or its agent or contractor, but not a Covered Entity nor a Government Health Care Entity
- A federal, state, local, or tribal agency, instrumentality, or other unit of government that determines whether an Individual qualifies for government benefits for any purpose other than health care (e.g SSD) or its agent or contractor acting on its behalf
- A Public Health Authority or its agent or contractor
- An Individual Access Service Provider
- Any entity that contracts with and enables connectivity for any of the entities listed above
- If an entity is not included but is entitled to receive information under the exchange purposes, submit a request to the RCE to add to this list.