Legal / Policy Requirements and Considerations of TEFCA

Rachel Abbey Mara Howard Williams Lillian Colasurdo

Trusted Exchange Framework

The **TEF** describes a common set of nonbinding, foundational principles for policies and practices to facilitate data sharing among health information networks.

Broad industry alignment with these principles can help entities enter into more uniform contractual relationships that are required for improved electronic flow of health information where and when it is needed.

The TEF includes seven principles:

Standardization

Openness and Transparency

Cooperation and Non-Discrimination

Privacy, Security, and Safety

Access

Equity

Public Health



The Common Agreement

- 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 an agreement that both the RCE signs and a QHIN 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.
 - TEFCA Flow-Down Resource available
- The Common Agreement incorporates the QHIN Technical Framework and the Standard Operating Procedures (SOPs).



Framework Agreements and TEFCA Connections

Common Agreement

Each QHIN voluntarily enters into the same contractual agreement with the RCE by signing the Common Agreement

Participant/Subparticipant Terms of Participation

All Participants and Subparticipants voluntarily agree to the Terms of Participation without modification as part of their agreements with their TEFCA connector

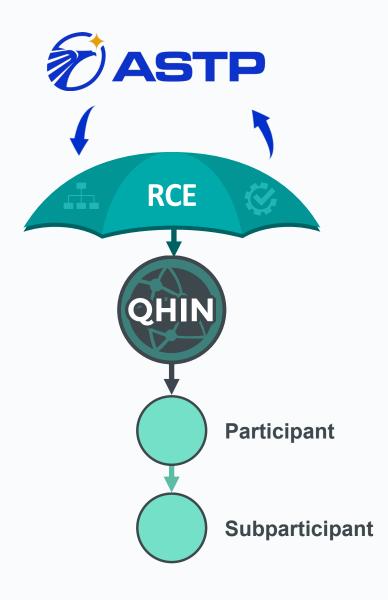
TEFCA connector

A QHIN, Participant, or Subparticipant that offers services to connect into TEFCA exchange

TEFCA connected entity

A QHIN, Participant, or Subparticipant that is bound to a Framework Agreement

Entities may connect into exchange at any level





Framework Agreements: Elements of the Participant/Subparticipant Terms of Participation

- Definitions and Relevant Terminology
- Cooperation and Non-Discrimination
- Confidentiality and Accountability
- RCE Directory Service and Directory Entries
- TEFCA Exchange Activities
- Individual Access Services
- Privacy
- Security
- General Obligations
- Term, Termination, and Suspension
- Contract Administration

The Terms of Participation bind all entities to the same "Rules of the Road"

<u>The Terms of Participation can be found</u> <u>in the Common Agreement on page 48</u>





U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION



TEFCA

Engaging with Legal Counsel

Lillian Colasurdo, JD, MELP

October 17, 2024



Why You Need Your Lawyer











Click the image for a link to each document.



Effective Legal Partnerships

- Patience
- Preparation
- Curiosity





TEFCA - Legal Considerations

Approach to TEFCA Participation

- There are different ways to participate in TEFCA.
- Understand your agency's overall goal. This will help you effectively partner with your legal counsel to understand the legal and compliance landscape, including any alternative approaches.

Legal Agreements

- While only QHINs sign the Common Agreement, Participants and Sub-participants must agree
 to certain flow-down provisions. These should be carefully reviewed by agency legal counsel.
- -Agency attorneys will require sufficient time to review all relevant legal agreements along with any supplemental materials (e.g., security standards or other policies and procedures).



TEFCA - Legal Considerations, contd.

Jurisdictional Limits on Data-Sharing

- Laws may limit data exchange by a jurisdiction, even for 'public health purposes'.
- —While all data exchanged under TEFCA is subject to "Applicable Law" (state, tribal, local, territorial, and federal law), and applicable law controls in any conflict with the Common Agreement (CA), ensuring compliance with local law is expected to be of primary concern to legal counsel.
- Data flow maps or diagrams can help identify the legal and compliance risks to participation (e.g., showing what the data is, what part of the agency it is coming from, where it is going, how it is transmitted, if and how it is stored, etc.) and help legal counsel analyze the proposed arrangement.
- Also, consider highlighting what the agency is sharing now and how that may change with TEFCA in discussions with legal counsel.

Additional Resources

- · 21st Century Cures Act
- Technical Exchange Framework: Principles for Trusted Exchange
- · Recognized Coordinating Entity (RCE) The Sequoia Project
- ASTHO Webinar: TEFCAOverview and Perspectives From the Field
- RCE Summary of Flow Down Provisions from Common Agreement
- RCE Common Agreement User Guide with Order of Precedent
- ASTHO Blog: TEFCA: A Better User Experience for Public Health Data
- · RCE Resources Library
- · CDC's data strategy





Questions?