



Understanding eHealth Exchange TEFCA Flowdowns and Protocols

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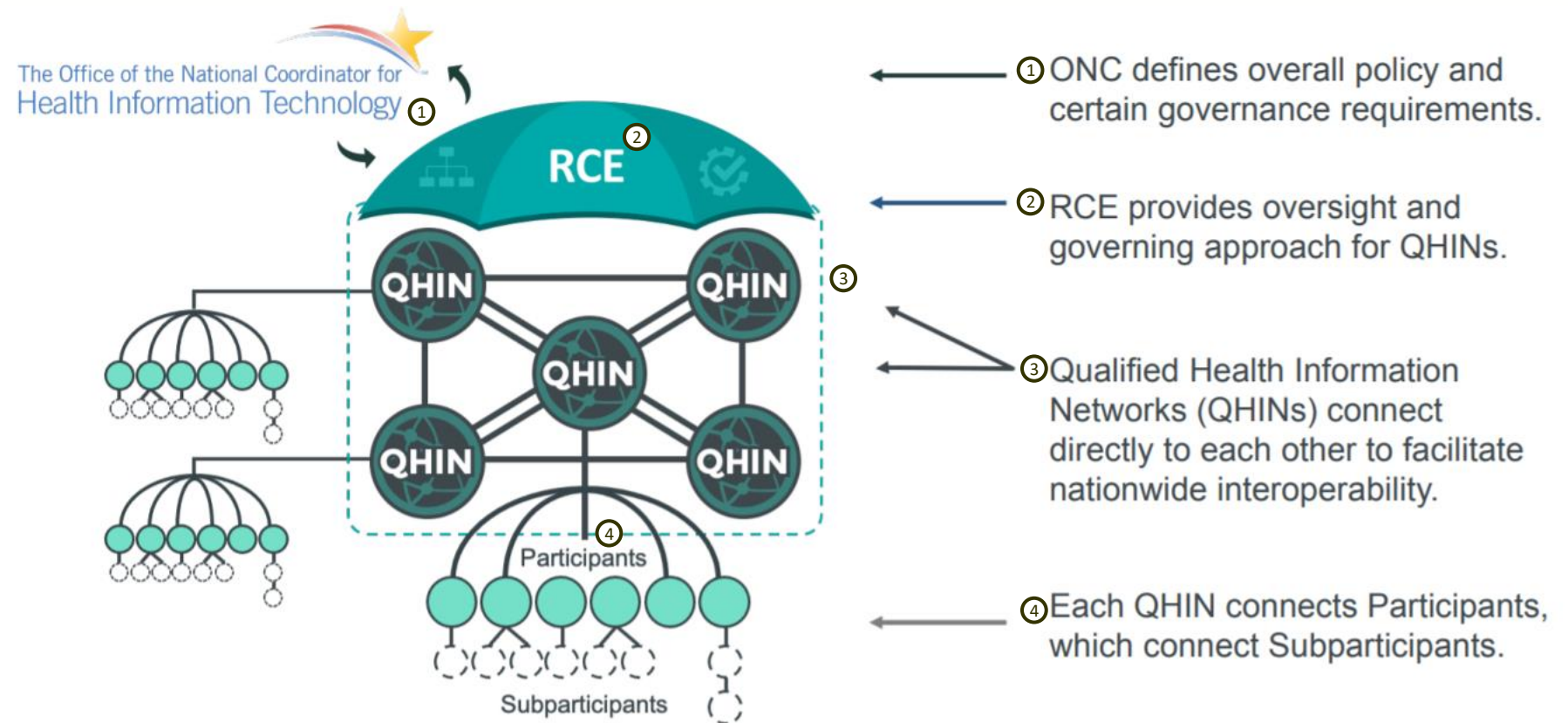
Agenda

- TEFCA Overview
- eHealth Exchange TEFCA Terms and Conditions
- eHealth Exchange TEFCA Protocols
 - Governance
 - Change Management
 - Security Incidents
 - Enforcement
 - Dispute Resolution
- Questions
- How to obtain additional information?



TEFCA Overview

How will TEFCA Work?



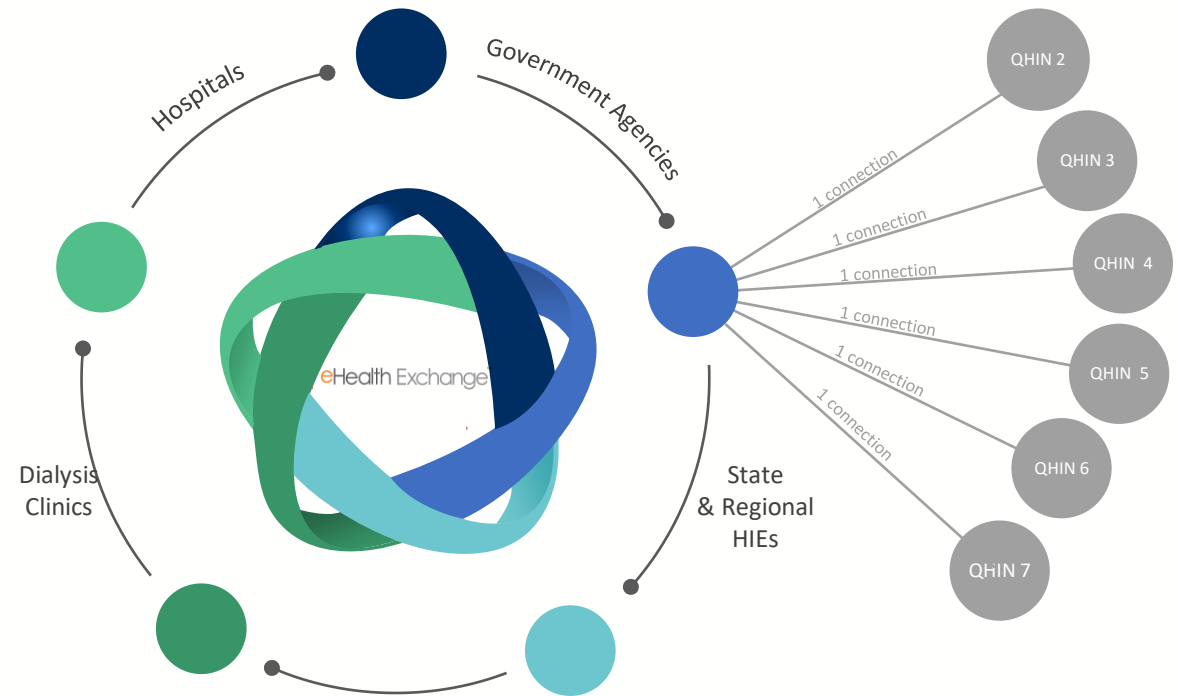
What is the Trusted Exchange Framework (TEFCA)?

It's a federally endorsed governance framework for **cross-network** exchange of healthcare records.

Similar to Carequality, it's a framework, and not a network:

- Technical & policy agreements
- Governing structure
- Federated architecture

Enables healthcare organizations connected to a TEFCA Qualified Health Information Network (QHIN) to exchange patient data with other healthcare organizations connected to other QHINs.



Which networks exchange via TEFCA?

The HHS announced that the [eHealth Exchange](#) is one of six applicants that have had their applications to become a Qualified Health Information Network (QHIN) approved

eHealth Exchange™

Epic

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It's not yet clear which healthcare organizations will agree to exchange via TEFCA. Will yours?

What's changing?

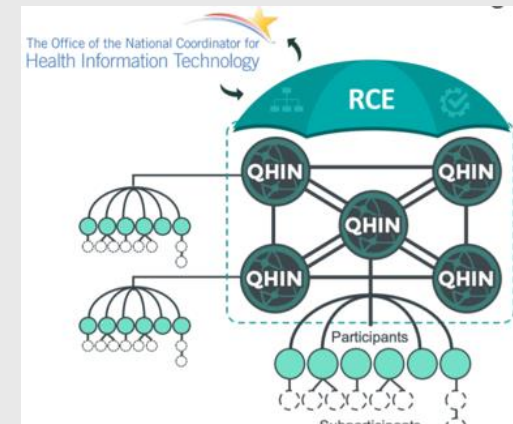
Prior to eHealth Exchange Connecting with TEFCA

Your organization can exchange with the eHealth Exchange's 320+ health systems, federal agencies, providers and provider collaboratives.



Once eHealth Exchange Goes Live on TEFCA

Option for your organization to **also** exchange with healthcare organizations participating in TEFCA QHINs.



eHealth Exchange go-live on TEFCA?

- eHealth Exchange and other QHINs must first complete TEFCA testing
- Multiple QHINs must be ready to go-live simultaneously.



Unless you ask administrator@ehealthexchange.org by the required date to NOT connect your organization to TEFCA, your Hub connection will connect your organization to TEFCA.

QHIN Required Responses

QHIN Participants and Sub-Participants must:

1. Respond to Treatment queries (effective immediately)
2. Respond to Individuals' requests (effective March 16, 2023, based on the IAS SOP publication on September 16, 2022)
3. Respond to Government Benefits Determination queries (effective date tbd)
4. Respond to Healthcare Operations (HCO) queries (effective date tbd)
5. Respond to Payment queries (effective date tbd)
6. Respond to Public Health queries (effective date tbd)
7. Adhere to the TEFCA FHIR Roadmap (under development)

Major Technical Differences eHealth Exchange QHIN Participants Must Support

1. Adopt USDCI v1 data classes and elements
2. Adhere to the Concise Consolidated CDA 1.1 Specification
3. Adhere to Postal Address Standards
4. Adopt IHE ITI Technical Framework Revisions 17.0 (versus Revision 8.0)
5. Accept aggregated XCPD responses
6. Various requirements such Purpose Of Use values, different consent attribute structure, sub-participant directory entries and detailed reporting, onboarding log submissions, specific test patients, and quarterly reporting.

Participant Opt-out Process Summary

1. OPP #10 requires the eHealth Exchange to allow existing Participants to “opt-out” of participating in the TEFCA QHIN
2. Coordinating Committee has directed eHealth Exchange staff to initiate the “opt-out” process by providing written notice to all Participants. The notice will include :
 - a. Common Agreement [Link to Common Agreement](#)
 - b. eHealth Exchange TEFCA Terms & Conditions (flow downs) [eHealth Exchange TEFCA Terms and Conditions](#)
 - c. eHealth Exchange TEFCA protocols (Being finalized with the RCE)
 - d. Dates for TEFCA education sessions (Being determined now)
 - e. eHealth Exchange Readiness Checklist
3. Participants will have at least 60 days after the date of the notice to **opt-out** of TEFCA exchange via the eHealth Exchange QHIN, or be deemed to be participating in the eHealth Exchange QHIN and bound by eHealth Exchange’s TEFCA terms.

Just as when eHealth Exchange joined Carequality, eHealth Exchange will make best efforts to ensure Participants who do not opt-out truly intend to exchange via eHealth Exchange’s QHIN.



eHealth Exchange TEFCA Terms and Conditions

Required Flow Downs: Common Agreement and DURSA Comparison

- The DURSA and the Common Agreement (CA) both incorporate the idea that certain requirements must be “flowed down” to the downstream customers of an eHealth Exchange or TEFCA Participant.
- The DURSA takes a pretty “high level” approach whereas the CA is much more detailed. Despite this difference in overall approach, there are similarities in the specific requirements that need to be “flowed down” between the DURSA and the CA. There are also differences.
- This slide deck presents a summary of these similarities and differences to help orient organizations that are considering participating in TEFCA via the eHealth Exchange, if the eHealth Exchange is designated as a QHIN.

TEFCA's approach to Required Flow Downs

- The Common Agreement takes a much more prescriptive approach to required flow downs.
- Specific sections of the Common Agreement are labeled as a “**Required Flow Down**” which means that the entire section must be flowed down by the Participant to its Subparticipants.
 - In some instances, the required flow down is one specific part of a section in the Common Agreement and that part is specifically labeled as a “Required Flow Down”
- The Common Agreement does require that Subparticipants flow down the Required Flow Downs to its Downstream Subparticipants, per the definition of the term “Required Flow Downs.”

Common Agreement – List of Required Flow-Downs

- 6.1 Cooperation
- 6.2.1 Prohibition Against Exclusivity
- 6.2.2 No Discriminatory Limits on Exchange of TI
- 7.1 Confidential Information
- 8.2 Utilization of the RCE Directory Service
- 9.2 Uses
- 9.3 Disclosures
- 9.4 Responses
- 9.5 Special Legal Requirements
- 10 Individual Access Services¹
- 11 Privacy
- 12.1.4 Participants and Subparticipants [Security]
- 12.2 TI Outside the United States
- 13.1 Compliance with Applicable Law and the Framework Agreements
- 13.2.2 Responsibility of Signatory
- 13.3 Flow-Down Rights to Suspend
- 13.4 Survival for Participants and Subparticipants

eHealth Exchange TEFCA Terms & Conditions

- These incorporate the ONC required flow-downs that **differ** from the DURSA requirements
- We created the Terms and Conditions to help eHealth Exchange Participants understand what the flow downs mean for them and their Subparticipants
- The Terms and Conditions provide Participants with a way to approach complying with the required flow-downs, every Participant that does not opt-out of TEFCA will be required to comply with these Terms and Conditions without any edits just like the DURSA

TEFCA Required Flow downs that differ from the DURSA (1 of 2):

- **6.2.1 Prohibition Against Exclusivity-** The CA prohibits any QHIN or its Participants from attempting to lock in a Subparticipant and preventing the Subparticipant from working with others for activities outside of TEFCA. The DURSA does not prohibit this.
- **6.2.2 No Discriminatory Limits on Exchange of TI-** The CA prohibits a QHIN or a Participant from limiting interoperability through the way that it manages its network. The DURSA does not specifically address this.
- **8.2 Utilization of the RCE Directory Service-** The CA includes specific restrictions about how QHINs implement and operate their Directory Service. The DURSA does not specifically address this.
- **9.4 Responses-** The CA requires support for **all** Exchange Purposes and they will become mandatory on the timeline determined by ONC. Treatment and Individual Access Services are mandatory immediately. The DURSA also has specific Permitted Purposes, but provides more flexibility about which Permitted Purposes a Participant supports.
- **10 Individual Access Services-** The CA specifically identifies this as an Exchange Purpose that is mandatory immediately. The DURSA Permitted Purposes do include a Permitted Purpose for exchange “in support of an individual’s right to access their health information”. However, this is not mandatory for any eHealth Exchange Participant. Also, the CA provides very specific requirements about IAS that the DURSA does not.

TEFCA Required Flow downs that differ from the DURSA (2 of 2):

- **12.3 Security Incident Notification-** The CA imposes an interesting reporting requirement by which a Participant, Subparticipant or Downstream Subparticipant must report any Security Incident “one level above and one level below” the reporting entity. The DURSA does not include this type of reporting requirement.
- **12.2 TI Outside the United States-** The CA places restrictions on a QHINs, Participants or Subparticipants ability to disclose TI outside the US. The DURSA does not have a similar restriction.
- **13.2.2 Responsibility of Signatory-** The CA requires each QHIN to take reasonable steps to assure that its Participants are complying with the Required Flow Downs and the SOPs. Participants have a duty to notify the QHIN and the Subparticipant if the Subparticipant is not complying. The DURSA does not have this requirement.
- **13.3 Flow-Down Rights to Suspend-** The CA gives the RCE the right to suspend QHINs and this flows down to Participants, Subparticipants and Downstream Subparticipants. This means that each QHIN has the same suspension rights as the RCE and the Participant has the same rights as the QHIN, on down the line. The DURSA differs by empowering the eHealth Exchange Coordinating Committee the authority to suspend Participants, but does not flow this down.

TEFCA Required Flow downs that are similar to the DURSA requirements (1 of 2):

- **6.1 Cooperation-** Both the DURSA and the CA have sections that require cooperation. The CA flow down is more specific than the DURSA general duty to cooperate.
- **9.2 Uses-** The DURSA refers to this as Future Use, but the substantive provisions are the same.
- **9.3 Disclosures-** The DURSA does not have a direct parallel section, but Section 13 covers the same issue. The DURSA has more granular requirements whereas the CA covers this under Applicable Law.
- **9.5 Special Legal Requirements-** The DURSA covers this in Section 13.
- **13.1 Compliance with Applicable Law and the Framework Agreements-** The DURSA contains the same requirements in Section 15.03 (Compliance with the DURSA) and Section 15.11 (Compliance with Laws). The CA does require Participants to take reasonable steps to assure that its Subparticipants comply and to inform its QHIN if it becomes aware that its Subparticipants are not in compliance.

TEFCA Required Flow downs that are similar to the DURSA requirements (2 of 2):

- **11 Privacy-** The CA recognizes that some QHINs, Participants or Subparticipants will be covered by HIPAA and will comply with HIPAA. For Non-HIPAA Entities (NHE), the CA lists specific sections of the HIPAA Privacy Rule with which the NHE must comply. The DURSA requires that any Participant that is not subject to HIPAA must comply with the HIPAA Privacy Rule provisions listed in Attachment 5 of the DURSA.
- **12.1.4 Participants and Subparticipants [Security]-** Both the CA and the DURSA require NHEs to comply with the HIPAA Security Rule. The TEFCA Security SOP adds additional requirements for QHINs, Participants and Subparticipants.
- **13.4 Survival for Participants and Subparticipants-** The CA and the DURSA require that specific listed sections of the respective agreements survive termination. This is pretty standard.

The DURSA's approach to Flow Downs (1 of 2):

- The DURSA approach to required flow downs is very “high level.”
- Section 15.04 requires each eHealth Exchange Participant to have valid and enforceable agreements with their Participant Users:
 - FYI: An eHealth Exchange Participant User is the functional equivalent to a TEFCA Subparticipant.

DURSA Flow Downs (2 of 2):

- The Participant agreements with its Participant Users **must** require the Participant Users to, at a minimum, do the following:
 - Comply with Applicable Law;
 - Cooperate with Participant on matters related to the DURSA;
 - Transact Message Content only for Permitted Purposes;
 - Use Message Content received from another Participant in accordance with the DURSA provisions;
 - Report Adverse Security Events to its Participant as soon as reasonably practical after determining that one has occurred;
 - Not disclose any passwords or other security measures issued to Participant User by Participant.
- A “Participant User” is broadly defined in the DURSA and would include a Participant’s customers as well as End Users.
However, the DURSA does not expressly require downstream agreements



eHealth Exchange TEFCA Protocols

eHealth Exchange TEFCA Protocols

- We want our Participants that do not opt-out of TEFCA to be able to comply with the requirements without having to spend a lot of time understanding the Common Agreement and SOPs
- The purpose of these Protocols is to provide additional details about the required flow-downs and guidance on what Participants need to do to comply with the flow-downs
- Initial Required Protocols:
 1. eHealth Exchange TEFCA Governance Protocol
 2. eHealth Exchange TEFCA Change Management Protocol
 3. eHealth Exchange TEFCA Security Incident Protocol
 4. eHealth Exchange TEFCA Enforcement Protocol
 5. eHealth Exchange TEFCA Dispute Resolution Protocol

eHealth Exchange TEFCA Governance Protocol

- This Protocol addresses the organization and operation of the QHIN Governance Committee (QGC) which will perform the functions of the eHealth Exchange QHIN Designated Network Governing Body (DNGB) as that term is defined in the QHIN Onboarding and Designation SOP.
- The eHealth Exchange Coordinating Committee, which is the governing body of the eHealth Exchange, will establish the QGC as a standing subcommittee with the authority specified in the Onboarding and Designation SOP, and the eHealth Exchange QHIN TEFCA Terms and Conditions and this Protocol.
- The QHIN Governance Committee will have responsibility, oversight, control, and final decision-making authority over each of the Governance Functions: (i) Technical framework of the Designated Network; (ii) The resolution of disputes regarding use of eHealth Exchange QHIN; (iii) eHealth Exchange QHIN Security Incident(s); (iv) enforcement of eHealth Exchange QHIN Participant compliance with all flow-down requirements, and: (v) change management to implement changes for the eHealth Exchange QHIN.

eHealth Exchange TEFCA Governance Protocol

Membership

Not less than five (5) and no more than eleven (11) total members

- One (1) member of the CC
 - Priority to a CC member who is affiliated with a Participant/Subparticipant that has indicated its intent to join the eHealth Exchange QHIN
- One (1) member of the Healtheway, Inc. Board
- eHealth Exchange QHIN Participants and Subparticipants Representatives (combined)
 - At least one (1) eHealth Exchange QHIN Participant and one (1) eHealth Exchange QHIN Subparticipant
- One (1) eHealth Exchange staff (ex officio)

eHealth Exchange TEFCA Change Management Protocol

- The QHIN Governance Committee shall establish and maintain reasonable Protocols. Protocols are those documents that describe the management, operation, and participation in the eHealth Exchange QHIN network. As may become necessary for the proper function of the eHealth Exchange QHIN network, the QHIN Governance Committee may establish new Protocols, and TEFCA Materials, or it may amend, repeal, and/or replace any existing Protocols and TEFCA Materials consistent with this Protocol and the TEFCA Terms and Conditions.
- This protocol addresses the requirements of notifying eHealth Exchange QHIN Participants of changes to any TEFCA requirements and eHealth Exchange TEFCA Materials to remain in compliance with TEFCA requirements to exchange Message Content on the eHealth Exchange QHIN Network.
- The TEFCA requirements include, but are not limited to, the TEFCA Protocols as driven by the Common Agreement (non-discretionary changes).
- The TEFCA Materials include, but are not limited to, the TEFCA Terms & Conditions, TEFCA Supplements and TEFCA Protocols (discretionary changes).

eHealth Exchange TEFCA Security Incident Protocol

- The primary purpose of this protocol is to provide standardized and clear methods and procedures for Participants to report any suspected TEFCA Security Incident. The privacy, security, and integrity of TEFCA Information are essential. To help maintain the privacy, security, and integrity of TEFCA Information and promote trust among QHINs, Participants, and Subparticipants, each eHealth Exchange QHIN Participant has agreed to notify certain other Participant, Subparticipants, the eHealth Exchange QHIN Chief Information Security Officer (CISO), and the QHIN Governance Committee of a TEFCA Security Incident.
- This protocol sets forth the procedure by which the eHealth Exchange Participant, the eHealth Exchange CISO, and the QHIN Governance Committee will fulfill their respective TEFCA Security Incident obligations under the TEFCA Terms & Conditions.

eHealth Exchange TEFCA Enforcement Protocol

- Compliance with the eHealth Exchange TEFCA Terms and Conditions is mandatory for Participants, Subparticipants and their Downstream Subparticipants as specified in the Terms and Conditions. When non-compliance is suspected, it must be investigated to determine the facts and evaluate the appropriate response that the QHIN Governance Committee should take.
- The QGC and management may discover compliance concerns through a variety of ways including, but not limited to, by receiving complaints from Participants or via its own monitoring of activity in the eHealth Exchange QHIN network.
- Participants are expected to make the QGC aware of concerns that they have about possible non-compliance by themselves, another Participant, their Subparticipants or their Downstream Subparticipants.
- If the QGC determines that a Participant, a Subparticipant or a Downstream Subparticipant has failed to comply with the TEFCA Terms and Conditions, the QGC must determine what steps should be taken to address the non-compliance. This may take the form of imposing a Corrective Action Plan, Suspension or Termination of a Participant.

eHealth Exchange Dispute Resolution Protocol

- The Common Agreement requires that QHINs attempt to resolve Disputes through “informal discussions” before invoking the Dispute Resolution Process created by the Common Agreement.
- The Dispute Resolution SOP provides details on the process of the Dispute Resolution Process that is administered by the RCE.
- Each QHIN is also required to have its own Dispute Resolution Process to address Disputes that arise within the QHIN.
- The eHealth Exchange TEFCA Terms and Conditions make clear that eHealth Exchange Participants shall follow the eHealth Exchange Dispute Resolution Process set forth in the DURSA **except** that Disputes involving an eHealth Exchange QHIN Participant and another eHealth Exchange QHIN Participant that arise exclusively out of the use of the Connectivity Services or a Dispute between the eHealth Exchange QHIN and a Participant may be escalated to the QGC instead of the eHealth Exchange Coordinating Committee.
 - This Protocol will provide specific guidance about how the eHealth Exchange QHIN Dispute Resolution Process will operate.



Questions?

How might I obtain additional information?

| How | When | Where |
|--|--|---|
| 1. Visit eHealth Exchange Web Site | Any time | https://ehealthexchange.org/what-we-do/tefca-and-ehealth-exchange |
| 2. Monthly Participant Web Meetings | Typically, the 3rd Thursday of Each Month at 1 pm ET | https://ehealthexchange.org/events |
| 3. Monthly TEFCA Policy Compliance Meetings | Dates coming soon! | https://ehealthexchange.org/events |
| 4. Monthly TEFCA Technical Compliance Meetings | Dates coming soon! | https://ehealthexchange.org/events |
| 5. Email | Any time if you have a specific question | administrator@ehealthexchange.org |

TEFCA Preview of TECHNICAL Requirements

- Friday March 17th at 1:00 EDT

Email administrator@ehealthexchange.org if you would like to attend and haven't received an invitation.

THANK YOU!