### **TEFCA Monthly eHealth Exchange Technical Webinar**

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# Agenda

- Monthly TEFCA Technical Webinars
- TEFCA Overview Reference
- XCPD Aggregated Responses Self-Test Tool
- QHIN Reporting and Volume Status
- eCR Public Health Reporting Via The eHealth Exchange QHIN Hub
- TEFCA New Common Agreement 2.0 Technical Considerations
- Open Discussion / Q&A
- For More Information (Including Office Hours)

#### eHealth Exchange

# Monthly TEFCA Technical Webinars

eHealth Exchange

### eHealth Exchange TEFCA Monthly Webinar Series

- Today's webinar is part of a series
- Prior webinars covered:
- TEFCA Readiness Checklist
- Individual Access Services Providers
- Reporting Requirements
- Error Handling
- And more

Prior webinars can be found at:

TEFCA Resources for eHealth Exchange Participant 📖 Webinars SEE TEFCA Checklist **TEFCA** Obligations (Includes Technical Obligations) A Register Now or View Past Eve View Resources **TEFCA Checklist Education** View Resources TEFCA Requirements Checklist Webinars eHealth Exchange TEFCA Terms June 12, July 14, July 31 and Conditions **Register Now**  June 12: View Recordin Change Management Protocol Slides Common Agreement for Nationwide Health Information **TEFCA Policy Sessions** Interoperability VI (Only eHealth June 20, July 10, July 24 **Register Now** Exchange signs) View Recording | Viev Dispute Resolution Protocol Monthly TEFCA Technical Enforcement Protocol May 2023 🗋 Governance Protocol View Slides | View R Operations and Reporting • June 2023 View Slides | View Re Protocol Security Incident Protocol

https://ehealthexchange.org/what-we-do/tefca-and-ehealth-exchange/

## eHealth Exchange Monthly TEFCA Technical Webinar Series

- May 2023 TEFCA Individual Access Services Providers Requirements
   <u>View Slides</u> | <u>View Recording</u>
- June 2023 TEFCA Directory, Errors, Logs, and Reporting Requirements
   <u>View Slides</u> | <u>View Recording</u>
- July 2023 TEFCA Draft Monthly and Quarterly Reports Review
   <u>View Slides | View Recording</u>
- August 2023 TEFCA Updates and Aggregated Patient Discovery Requirement
   <u>View Slides</u> | <u>View Recording</u>
- September 2023 TEFCA Hub Development Updates
   <u>View Slides</u> | <u>View Recording</u>
- October 2023 Validation Status for the eHealth Exchange Hub, Individual Access Services Provider (IAS) SAML Simplifications, Lesson's Learned, New potential
   Purpose of Use
   View Slides Lyliew Decerding
  - View Slides | View Recording
- November 2023 TEFCA FHIR Support, TEFCA Hub Technical Readiness, New QHIN Technical Framework, TEFCA Directory, Lessons Learned from Initial Sub-Participants
- TEFCA Reporting Requirements: RCE Updates
   <u>View Slides | View Recording</u>
- December 2023 ONC/HHS/RCE Announcement, Updated FHIR Roadmap for TEFCA Exchange, TEFCA Hub Technical Readiness
   <u>View Slides | View Recording</u>
- TEFCA Checklist Education Webinars
- June 12: <u>View Recording</u> | <u>View Slides</u>
- July 14: View Recording
- July 31: <u>View Slides</u>
- Source: <u>https://ehealthexchange.org/what-we-do/tefca-and-ehealth-exchange/</u>

# ONC/HHS/RCE Announcement



« NEWS

eHealth Exchange Among First To Achieve TEFCA<sup>s</sup> Qualified Health Information Network<sup>™</sup> (QHIN<sup>™</sup>) Designation

Today, **eHealth Exchange** announced it's been designated as a Qualified Health Information Network<sup>™</sup> (QHIN<sup>™</sup>) under the Trusted Exchange Framework and Common Agreement<sup>™</sup> (TEFCA<sup>™</sup>). This places eHealth Exchange's electronic data-sharing network among the country's first Designated QHINs to go live and operationally ready for exchange with other Designated QHINs.

lealthIT.gev		Official Website of The Office of the N	lational Coordinator for Health Informati	on Technology (ONC)	
		nteroperability > Policy > TEFCA	TOPICS V BLOG	NEWS 🗸 DATA ABOUT ONC 🗸	Q
Interoperability					
Policy		Trusted Exchange Framework	work and Common Ag	reement (TEFCA)	
TEFCA					
Information Blocking			4 U.S. Department of		Q Q
Interoperability 2030		TEF _	Health and H	luman Services	Enter the terms you wish to search for.
Advancing Interoperability with Medicaid			Enhancing the health an		
lealth IT Certification		ONC released Version 2.0 of the Common Ag	About HHS Programs & Services	Grants & Contracts Laws & Regulations	
andards and Technology		published in November 2023, and includes en Resources (FHIR <sup>®</sup> ) based transactions. The Co	About HHS Programs & Services	a powing the Wa	v for TEFCA Exchange via FHIR
estments	> >	sets forth the requirements each Participant a ToPs incorporate all applicable standard opera	Home > About > News > ONC Re	leases Common Agreement Version 2.0, Paving the Wa	T+ 🖶 😚 💥 🐸
		The Trusted Exchange Framework on the	News		
		and the interoperability (2) to at the	Blog		Contact: HHS Press Office
		, and generate health care value;	HHS Live	FOR IMMEDIATE RELEASE	202-690-6343
		TEFCA Components		April 22, 2024	media@hhs.gov
		Common Agreement	Podcasts		
		The Common Agreement is the agreement that the	Media Guidelines for HHS Employees		the operation
		Agreement also establishes the information			non Agreement Version 2.0, Paving
		and an		ONC Releases Comm	
		Trusted Exchange Framework		the Way for TEFCA E	xchange via Filit
		The Trusted Exchange Framework is a common set of enable widespread information exchange. These pri privacy, security, and safety; access: equity; and such			n Services (HHS), through the Office of the National Coordinator for Health cognized Coordinating Entity <sup>®</sup> (RCE <sup>™</sup> ), The Sequoia Project, Inc.,

#### Meet the Designated QHINs

Below are organizations that have successfully completed the Qualified Health Information Network<sup>TM</sup> (QHIN<sup>TM</sup>) onboarding process and are recognized as Designated QHINs for TEFCA exchange. There are additional Candidate QHINs still in the onboarding phase listed <u>here</u>.



#### Meet the Candidate QHINs

Looking for a list of **Designated QHINs**?

Below are organizations that have completed the Qualified Health Information Network<sup>TM</sup> (QHIN<sup>TM</sup>) application and have been accepted into the project planning and testing phase of the onboarding and designation process. Inclusion on this page is not an endorsement and does not guarantee that an organization will be Designated as a QHIN<sup>TM</sup>.



#### Sources:

https://rce.sequoiaproject.org/designated-qhins/ https://rce.sequoiaproject.org/candidate-qhins/

# eHealth Exchange is a Designated QHIN under TEFCA

eHealth Exchange is among the country's first Qualified Health Information Networks (QHINs) to achieve designation status under ONC's Trusted Exchange Framework and Common Agreement, also known as TEFCA.

We're ready to help HIEs, health systems, digital health platforms, and others who want to connect to the federally-endorsed TEFCA network.

TEFCA RESOURCES 🖿

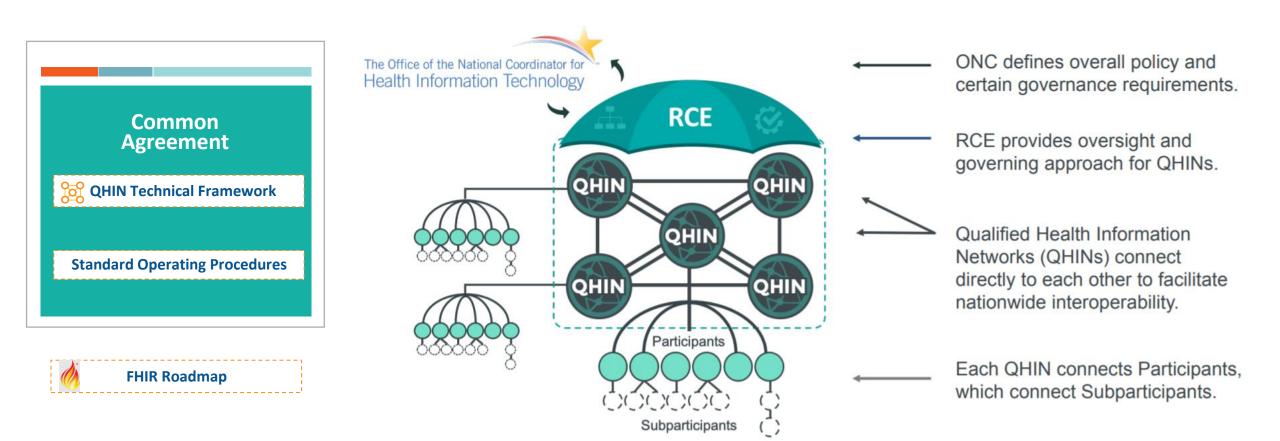
FAQS 🗖

CONTACT US 🖂

# **TEFCA Overview - Reference**

eHealth Exchange

### How Does TEFCA Work?



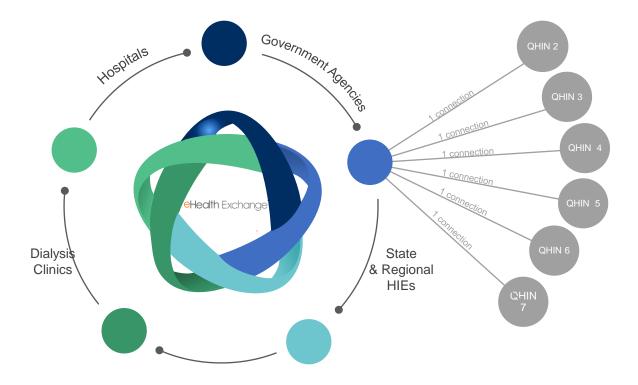
### What is the Trusted Exchange Framework (TEFCA)?

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

Similar to Carequality, it's a framework, and <u>not</u> 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.



Leveraging the power of the federal government to expand & mature interoperability

#### Intent to Exchange from 11 HIEs Operating in 15 States Serving up to 126 Million Patients

**ISP** EORGIA HEALTH NFORMATION Indiana Health NETWORK Shared Services erving Communities Hea Information Organization Information Exchange Community Interoperability Since 1996 BIG SKY CARE CONNECT Manifest MEDEX Healt Record FROM NUMBERS TO KNOWLEDGE **contexture**<sup>\*\*</sup> CyncHealth Creating connections. Improving lives.

eHealth Exchange

DESIGNATED

### What's changed?

Before: eHealth Exchange Connected with TEFCA

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



#### After: eHealth Exchange Went Live on TEFCA

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



### How is the eHealth Exchange different?

#### eHealth Exchange

- National non-profit focused on the Public Good
- Single technical connection instead of hundreds
- ✓ Vendor agnostic
- ✓ 24x7x365 monitoring
- ✓ Enforced content quality assurance
- ✓ Analytics dashboard
- ✓ Broad federal agency connectivity
- ✓ Trust (no patient tracking, no selling data)

#### **Other Networks**

- Multiple technical connections
- ▲ Vendor specific
- Limited to no 24x7x365 monitoring
- No mandatory content testing
- No or limited analytics portal dashboard
- No broad federal agency connectivity

XCPD Aggregated Responses New: Self-Service XCPD Aggregated Response Test Harness



# Aggregated XCPD Responses

- See slides and recording from April 2024 for detailed background information
- New: Self-Testing Tool Walkthrough
- Updated Next Steps Recommendations

XCPD Aggregated Responses	Martine	With Interview         Based and the state of the st	<complex-block></complex-block>
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21	222	<section-header><text><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><text><text><text><text></text></text></text></text></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></text></section-header>	Agregated SCPD Response Sequence Diagram Interactive In

19



### Aggregated XCPD Responses Use Cases

There are two scenarios where an eHealth Exchange XCPD (PD) initiating gateway may receive an XCPD Aggregated Response:

- 1) eHealth Exchange in-network "group query", "geospatial query"
- 2) TEFCA QHIN responses to eHealth Exchange Participants using a QHIN "broadcast query"

Note that the QHIN appears to allow for a single OR and aggregated XCPD response depending on the internal architecture of the QHIN (MPI or no-MPI).

Aggregated responses are not returned for TEFCA "targeted queries".

This is a likely breaking change

# Is Support for Aggregated XCPD Responses Mandatory?

As an eHealth Exchange Participant Initiating an XCPD request:



 For eHealth Exchange in-network transactions, support for Aggregated XCPD responses is NOT required. However, group query and geospatial query responses will not be fully available to initiators not supporting Aggregated XCPD responses.



For TEFCA, support for Aggregated XCPD responses IS required.

### Aggregated XCPD Response Testing

#### NOW AVAILABLE

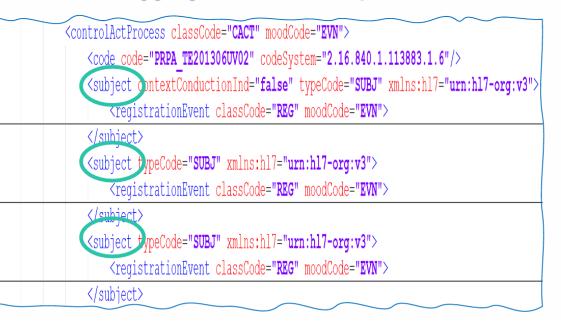
Test your ability to consume and process an aggregated Patient Discovery response!

https://hub001val.ehealthexchange.org/ehx/1.0.0/iti55/2.0?\_eHxHubRouteTo=GeoStateTEST

**Test Patient Demographics** 

given	NWHINONE	
family	NWHINZZZTESTPATIENT	
birthdate	1/1/1981	
gender	Μ	
address	1100 Test Street	
city	Helena	
state	AL	
postal code	35080	

#### Aggregated XCPD Response



# Suggested Next Steps

- Determine if your gateway technology supports this standardsbased feature
  - Use the new eHealth Exchange test harness to assess your system's compatibility with Aggregated XCPD responses
- Work with eHealth Exchange staff to
  - Understand the impact if your technology platform does not support aggregated XCPD responses



Create an action plan

# **QHIN Reporting and Volume Status**

### As Mandated by QTF v1.1 QTF-124

eHealth Exchange

### QHIN-to-QHIN Reporting and Volume Status – April 2024

#### As Responding Gateway

#### Average response time for each QHIN-Participant transaction by HCID

үүүү-мм	eHx Responding	eHx Responding	Message	Average
T T T T-MIM	🌌 🔹 Par <u>ticipant Na</u> me 🔽	Participant HCID 🔽	Туре 🔽	🔹 🛛 Response Time 💌
2024-04			ITI-55	1.01
2024-04			ITI-38	0.46
2024-04			ITI-39	3.16
2024-04			ITI-80	n/a
2024-04			ITI-55	1.31
2024-04			ITI-38	0.79
2024-04			ITI-39	n/a
2024-04			ITI-80	n/a

#### Total number of messages received via QHIN Message Delivery

ΥΥΥΥ-ΜΜ	Documents			
TTTT-MIM	<b>.</b>	Received	-	
2024-04		0		



### eHealth Exchange QHIN Volume Metrics

#### eHealth Exchange QHIN Transaction Volume – As A Responder (April 2024)

Transaction Type	Patient Discovery Requests from Other QHINs to eHealth Exchange QHIN	% NOT Matched Due to Out of Service Area	Requests from Other QHINs Forwarded to eHx QHIN Participants	eHealth QHIN Participant Match Results	Avg Response Time in Seconds (eHx Hub + Participant)
Patient Discovery	9,950,727 15%↑	99.7%	~31,877 (0.3%)	~25,684 (81%)	1.15
Document Query	n/a	n/a	<b>8,320</b> 95%↑	2,559 clinical documents Identified	0.69
Document Retrieve	n/a	n/a	928 74%↑	924 clinical documents retrieved	3.16

1. 1. 1. Month-over-month percentage change in **total requests** has been added

2. Our QHIN Participants are not yet initiating requests, but at least one may be initiating by end of May

3. Interestingly, after the eHealth Exchange QHIN returns patient matches to one vendor via TEFCA, that vendor initiates QD & RD through the traditional eHealth Exchange network (not through TEFCA network).

# eCR Public Health Reporting Via The eHealth Exchange QHIN Hub

eHealth Exchange

### eCR Public Health Reporting Via The eHealth Exchange QHIN Hub

- APHL AIMS has officially opted-in to exchange under TEFCA with the eHealth Exchange as its QHIN
- The goal to begin exchanging for eCR under TEFCA is July 1, 2024
- The eHealth Exchange, APHL AIMS and a vendor are all working together to meet the stated deadline for eCR exchange
- Testing is underway with AIMS and the eHealth Exchange with informal reportability response testing with a vendor
- We have completed our first major milestone for eCR preparation and are working on our second milestone now



# **TEFCA New Common Agreement 2.0**

### Technical Considerations Version 2.0 Published 2024-04-22

U.S. Department of Health and H Enhancing the health an	d well-being of all Americans	arch for.			Q	
About HHS Programs & Services	Grants & Contracts Laws & Regulations eases Common Agreement Version 2.0, Paving the Way for TEFCA Exchange via FHIR	T+	ē	0	×	M
News				offi		
Blog		Contact: HHS Press Office 202-690-6343				
HHS Live	FOR IMMEDIATE RELEASE	media@hhs.gov				
Podcasts	April 22, 2024					
Media Guidelines for HHS Employees	ONC Releases Common Agreement the Way for TEFCA Exchange via FH	Version	12.	0,1	Pav	in



# Common Agreement v1.1 v 2.0

- Context
- High-Level Changes
- Detailed Technical Changes
- Comparing:
  - <u>https://rce.sequoiaproject.org/wp-content/uploads/2023/11/Common-Agreement-v1.1.pdf</u>
  - <u>https://rce.sequoiaproject.org/wp-content/uploads/2024/04/Common-Agreement-v2.0\_508-1.pdf</u>
- Out of Scope: Policy, Legal and Other Non-Technical Topics

# Published in the Federal Register 2024-05-01

• Source:

https://www.federalregiste r.gov/documents/2024/05/ 01/2024-09476/notice-ofpublication-of-commonagreement-fornationwide-healthinformationinteroperability-common

• Pages: 35107-35182



#### Notice

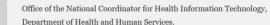
#### Notice of Publication of Common Agreement for Nationwide Health Information Interoperability (Common Agreement) Version 2.0

A Notice by the Health and Human Services Department on 05/01/2024

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#### PUBLISHED DOCUMENT

E AGENCY:



- ACTION:
- Notice.

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#### SUMMARY:

This notice fulfills an obligation under the Public Health Service Act (PHSA) that requires the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public internet website, and in the **Federal Register**, the trusted exchange framework and common agreement developed under the PHSA. This notice is for publishing an updated version of the Common Agreement (Version 2.0).

#### FOR FURTHER INFORMATION CONTACT:

Mark Knee, Office of the National Coordinator for Health Information Technology, 202-664-2058.

#### SUPPLEMENTARY INFORMATION:

This notice fulfills the obligation under section 3001(c)(9)(C) of the Public Health Service Act (PHSA) (42 U.S.C. 300jj-11(c)(9)(C)) to publish the trusted exchange framework and common agreement, developed under section 3001(c)(a)(b) of the PUSA (act USAC agree in a(c)(2)(2)) in the Endered Bariater. This



OCUMENT DETAILS

Printed version

DOCUMENT DETAILS

#### OCUMENT STATISTICS

Page views: 54 as of 05/14/2024 at 2:15 pm EDT

DOCUMENT STATISTIC

### New TEFCA Common Agreement v2.0







### Additional Updates In Process From The RCE

#### Applicable Law (federal, state, local, territorial, etc.)

Framework Agreements – Expected April 2024

Common Agreement (QHINs) Terms of Participation (Participants/Subparticipants)

QHIN Technical Framework Expected Mid June Standard Operating Procedures (SOPs) Expected June - July

### **Expected SOP Batch Releases**

<b>Batch 1</b> Published on ONC website in April (Effective: 60 days after publication in Federal Register)
Common Agreement Version 2.0 Terms of Participation (ToP)



### Transition from Version 1.1 to Version 2.0

- TEFCA is currently live on Common Agreement Version 1.1 for QHINs
- Applicable Flow-Down provisions are applied to Participants and Subparticipants
- There is a transition period to allow for adoption of the new Framework Agreements by those who are already live

   60 days for the Common Agreement
   180 days for the Terms of Participation
- During the transition all TEECA connected antition can appear in TEECA Evolution
- During the transition, all TEFCA connected entities can engage in TEFCA Exchange for approved Exchange Purposes
- QHINs are responsible for adding new TEFCA connected entities to the RCE Directory as they sign the Terms of Participation

April 2024	June 2024	Summer 2024	December 2024
<ul> <li>Expected Publish of final Common Agreement and Terms of Participation in Federal Register</li> </ul>	<ul> <li>Common Agreement 2.0 is effective for QHINs (60 days after publication)</li> </ul>	<ul> <li>Additional SOPs are released on a rolling basis</li> </ul>	<ul> <li>Terms of Participation are effective for all Participants and Subparticipants</li> </ul>
	<ul> <li>Final QTF version 2.0 published and expected to be in production</li> </ul>		
	<ul> <li>Facilitated FHIR SOP expected to be published and in production</li> </ul>		

## Key Concepts that have Evolved: Common Agreement Version 1.1 to Version 2.0

Common Agreement and QTF Version 1.1	Proposed Common Agreement and QTF Version 2.0
Fundamental requirements and components of TEFCA mostly included within Common Agreement and QTF Version 1.1	More details moved to SOPs
Model Participant/Subparticipant flow-down terms	Static Participant/Subparticipant Terms of Participation
Exchange only occurs QHIN-to-QHIN via IHE protocols	Facilitated FHIR available between Participants/Subparticipants
Exchange within QHINs not considered TEFCA exchange	TEFCA Exchange identified by unique TEFCA code
Six (6) authorized Exchange Purposes (XPs)	Six (6) authorized Exchange Purposes (XPs) with new sub exchange purposes and implementation guidance
Two (2) XPs require a response: Treatment and Individual Access Services (IAS)	Three (3) XPs require a response: Treatment, IAS, and Health Care Operations SubXP-1 (FHIR only)
All QHINs, Participants, and Subparticipants must respond	Introduction of Principal/Delegate roles and requirements
Participants and Subparticipants may not participate with more than one QHIN	Participants and Subparticipants may conduct TEFCA Exchange in multiple QHINs using multiple Nodes
Privacy/security obligations apply to all	Privacy/security obligations apply to all



# Policy/Technical Advisory Group

- **Purpose:** Serve as an **Advisory Group** to the Transitional Council to deliberate and review proposed amendments to the Common Agreement v2, the QTF v2, and associated SOPs.
- Responsibilities:
  - » Review proposed amendments to the Common Agreement v2, the QTF v2, and associated SOPs and provide feedback to the RCE and ONC on the proposed changes.
    - The feedback is intended to be advisory only and the RCE and ONC are not required to incorporate any specific feedback into the draft Common Agreement Version 2.0.
  - » Discuss practical and operational implementation questions and considerations that arise from policy and technical requirements across TEFCA.
- **Composition:** Continuation of the Applicant QHIN, QHIN, and Participant/Subparticipant Representative(s) involved in the Policy/Technical Working Group.
- **Timing and cadence:** The group will meet weekly until the formation of the caucuses, at which point we will re-assess timing and cadence.
- **Next Steps**: RCE will distribute draft charter to the Transitional Council for feedback and vote

### Summary of Stakeholder Feedback Received

#### **Participation in Multiple QHINS**

- Support for flexibility to allow Participation through multiple QHINs
- Desire for additional flexibility from what was proposed

#### **Principal/Delegate**

- Broad support for defining Principal/Delegate roles with some recommendations for clarification
- · Support for delineating between initiating and responding systems

#### **Terms of Participation Transition**

• Recommendation to provide transition period for Participants/Subparticipants to adopt Terms of Participation

#### **FHIR® Based Exchange**

- Recommendation to allow for transition period to adopt widescale FHIR using UDAP, including allowing for multiple approaches for Facilitated FHIR in the interim
- Recommendations to clarify FHIR US Core Version

### Summary of Stakeholder Feedback Received

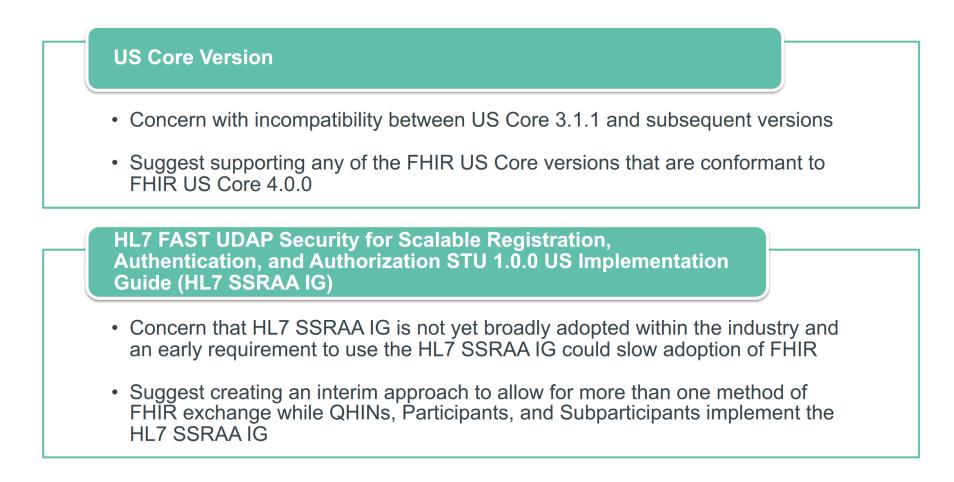
#### Health Care Operations SubXP SOP

- Varied views on scope of Health Care Operations SubXP:
  - Some desire to narrow use-cases while others support broader definition
  - General concern for Response requirements for HCO SubXP when using FHIR

#### Public Health SubXP SOP

- Public Health is seen as a valuable Exchange Purpose
- RCE received input on a variety of uses cases, including Electronic Case Reporting, Electronic Report, and Case Investigation
- The RCE is working closely with the CDC and ONC on alignment of TEFCA Exchange to optimize support for Public Health and expand educational efforts

### Stakeholder Feedback on Facilitated FHIR® Proposals



Source: https://rce.sequoiaproject.org/wp-content/uploads/2024/03/Final\_RCE-Monthly-Informational-Call-3-19-202415-Read-Only.pdf

### FHIR® Early Production Goals

Create an interim approach, starting in 2024, to enable FHIR Early Adopters to do Facilitated FHIR using more than one method for registration, authentication, and authorization.

Provide a roadmap to adopt a consistent, widescale approach to Facilitated FHIR with sufficient lead time for implementation.

Source: https://rce.sequoiaproject.org/wp-content/uploads/2024/03/Final\_RCE-Monthly-Informational-Call-3-19-202415-Read-Only.pdf

# FHIR® Early Production Standard Operating Procedure (SOP)

- The SOP will detail the allowable methods of FHIR for registration, authentication, and authorization through December 31, 2025, including:
  - » HL7 FAST UDAP Security for Scalable Registration, Authentication, and Authorization STU 1.0.0 US Implementation Guide (HL7 SSRAA IG)
  - » SMART Application Launch Framework Implementation Guide (SMART) Release 1.0.0
  - Some other authentication and authorization framework that adheres to the requirements of the QTF based on out-of-band arrangements between exchange partners including manual registration
- After January 1, 2026, all TEFCA Exchange using FHIR will use HL7 SSRAA FHIR IG Release 1.0.0
- FHIR exchange will comply with US Core v4.0.0

Office of the National Coordinator for Health Information Technology



#### Common Agreement for Nationwide Health Information Interoperability

Version 1.1

November 2023

Office of the National Coordinator for Health Information Technology



#### Common Agreement for Nationwide Health Information Interoperability

Version 2.0

April 2024

### New Definition: Breach of Unencrypted IAS Information

Breach of Unencrypted Individually Identifiable Information: the acquisition, access, or Disclosure of unencrypted Individually Identifiable Information maintained by an IAS Provider that compromises the security or privacy of the unencrypted Individually Identifiable Information.



### New Defined Term: FHIR Endpoint

FHIR Endpoint: has the meaning assigned to such term in the Health Level Seven International<sup>®</sup> (HL7<sup>®</sup>) Fast Healthcare Interoperability Resources (FHIR<sup>®</sup>) Specification available at https://hl7.org/fhir/r4/, as such specification may be amended, modified or replaced.

### Revised Definition of an 'Individual'

#### OLD

#### Individual: one or more of the following:

- (i) An individual as defined by 45 CFR 160.103;
- (ii) Any other natural person who is the subject of the information being Requested, Used, or Disclosed;
- (iii) A person who legally acts on behalf of a person described in paragraphs
   (i) or (ii) of this definition in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g);
- (iv) A person who is a legal representative of and can make health care decisions on behalf of any person described in paragraphs (i) or (ii) of this definition; or
- (v) An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (i) or (ii) of this section or the individual's estate under Applicable Law.

#### New

#### Individual: has the meaning assigned to such term at 45 CFR § 171.202(a)(2).

### Revised Definition of an 'Individual'

#### https://www.law.cornell.edu/cfr/text/45/171.202

(a) Definitions in this section.

(1) The term *HIPAA Privacy Rule* as used in this section means 45 CFR parts 160 and 164.

(2) The term *individual* as used in this section means one or more of the following—

(i) An individual as defined by 45 CFR 160.103.

(ii) Any other natural <u>person</u> who is the subject of the <u>electronic health information</u> being accessed, exchanged, or used.

(iii) A <u>person</u> who legally acts on behalf of a <u>person</u> described in paragraph (a)(1) or (2) of this section in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g).

(iv) A <u>person</u> who is a legal representative of and can make health care decisions on behalf of any person described in paragraph (a)(1) or (2) of this section.

(v) An executor, administrator, or other <u>person</u> having authority to act on behalf of a deceased <u>person</u> described in paragraph (a)(1) or (2) of this section or the individual's estate under State or other law.

### New Defined Terms: 'IAS Incident' and 'IAS Consent'

Individual Access Services Incident (IAS Incident): a TEFCA Security Incident or a Breach of Unencrypted Individually Identifiable Information maintained by an IAS Provider.

IAS Consent: an IAS Provider's own supplied form for obtaining express written consent from the Individual in connection with the IAS.

### New Actor Names: Initiating, Passthrough, Responding Nodes

Initiating Node: a Node through which a QHIN, Participant, or Subparticipant initiates transactions for TEFCA Exchange.

**Node**: a technical system that is controlled directly or indirectly by a QHIN, Participant, or Subparticipant and that is listed in the RCE Directory Service.

**Passthrough Node:** a Node that is neither an Initiating nor Responding Node and through which a QHIN, Participant, or Subparticipant transmits transactions to and from Initiating and Responding Nodes, including any other services it provides.

**Responding Node**: a Node through which the QHIN, Participant, or Subparticipant Responds to a received transaction for TEFCA Exchange.



### New Defined Term 'Security Posture'

**Security Posture:** the security status of an entity's networks, information, and systems based on information assurance resources including, without limitation, people, hardware, software, and policies, and capabilities in place to manage the defense of the entity's networks, information, and systems and to react as the situation changes (derived from NIST Definition 800-30r1).



### New Defined Term 'XP Code'

# XP Code: the code used to identify the XP in any given transaction, as set forth in the applicable SOP(s).



### Mandatory Response Text (Moved to an SOP)

In the below excerpt, the text with a blue background is new:

9.4 <u>Responses</u>. Except as otherwise set forth in an applicable SOP, Responding Nodes must Respond to Queries for all XP Codes that are identified as "required" in the

applicable SOP(s). Such Response must include all Required Information. Notwithstanding the foregoing, Signatory may withhold some or all of the Required Information to the extent necessary to comply with Applicable Law.

### New: IAS Multiple Services Providers Considerations

#### 10. Individual Access Services.

10.1 Individual Access Services (IAS) Offering(s). Signatory may elect to be an IAS Provider by offering IAS to any Individual in accordance with the requirements of this Section 10 and in accordance with all other provisions of this Common Agreement. Nothing in this Section 10 shall modify, terminate, or in any way affect an Individual's right of access under the HIPAA Privacy Rule at 45 CFR § 164.524 with respect to any QHIN, Participant, or Subparticipant that is a Covered Entity or a Business Associate. Nothing in this Section 10 of this Common Agreement shall be construed as modifying or taking precedence over any provision codified in 45 CFR Part 171. An IAS Provider shall not prohibit or attempt to prohibit any Individual using the IAS of any other IAS Provider or from joining, exchanging with, conducting other transactions with any other networks or exchange frameworks, using services

other than the IAS Providers' Designated Network Services, concurrently with the QHIN's, Participant's, or Subparticipant's participation in TEFCA Exchange.

### New: IAS Provider Consent Considerations

10.2 Individual Consent. This Section 10.2 shall apply to Signatory if Signatory is an IAS Provider. The Individual requesting IAS shall be responsible for completing the IAS Consent. The IAS Consent shall include, at a minimum: (i) consent to use the Individual Access Service; (ii) the Individual's acknowledgement and agreement to the IAS Provider's Privacy and Security Notice; and (iii) a description of the Individual's rights to access, delete, and export such Individual's Individually Identifiable Information. An IAS Provider may implement secure electronic means (e.g., secure e-mail, secure web portal) by which an Individual may submit the IAS Consent. An IAS Provider shall collect the IAS Consent prior to the Individual's first use of the IAS and prior to any subsequent use if there is any material change in the applicable IAS Consent, including the version of the Privacy and Security Notice referenced therein. Nothing in the IAS Consent may contradict or be inconsistent with any applicable provision of this Common Agreement or the SOP(s). If the IAS Provider is a Covered Entity and has a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520, the IAS Provider is not required to have a Privacy and Security Notice that meets the requirements of the applicable SOP. Nothing in Section 10 reduces a Covered Entity's obligations under the HIPAA Rules.



### **Revised IAS Provider Security Requirements**

- Blue background text is new. Red background text was removed. Green text was moved.
- Version 1.1 text:
- 10.5. Additional Security Requirements for IAS Providers (Required Flow-Downs). In addition to meeting the applicable security requirements set forth in Section 12, if Signatory is an IAS Provider it must further satisfy the requirements of this subsection.
  - 10.5.1. <u>Scope of Security Requirements.</u> If Signatory is an IAS Provider it must comply with the applicable security requirements set forth in this Common Agreement and the security SOPs for **all** Individually Identifiable information they hold, regardless of whether such information is TI.
  - 10.5.2. <u>Encryption.</u> If Signatory is an IAS Provider it is required to encrypt **all** Individually Identifiable information held by Signatory, both in transit and at rest, regardless of whether such data are TI.

### Revised IAS Provider Security Requirements (Contd.)

- Blue background text is new. Red background text was removed. Green text was moved.
- Version 1.1 text:

- 10.5.3. <u>TEFCA Security Incident Notice to Affected Individuals.</u> Each Signatory that is an IAS Provider must notify each Individual whose TI has been or is reasonably believed to have been affected by a TEFCA Security Incident involving the IAS Provider. Such notification must be made without unreasonable delay and in no case later than sixty (60) days following Discovery of the TEFCA Security Incident. The notification required under this section must be written in plain language and shall include, to the extent possible:
  - A brief description of what happened, including the date of the TEFCA Security Incident and the date of its Discovery, if known;
  - A description of the type(s) of Unsecured TI involved in the TEFCA
     Security Incident (such as whether full name, Social Security
     number, date of birth, home address, account number, diagnosis,
     disability code, or other types of information were involved);
  - (iii) Any steps Individuals should take to protect themselves from potential harm resulting from the TEFCA Security Incident;

### Revised IAS Provider Security Requirements (Contd.)

- Blue background text is new. Red background text was removed. Green text was moved.
- Version 1.1 text:

- A brief description of what the Signatory involved is doing to investigate the TEFCA Security Incident, to mitigate harm to Individuals, and to protect against any further TEFCA Security Incidents; and
- (v) Contact procedures for Individuals to ask questions or learn additional information related to the TEFCA Security Incident, which shall include a telephone number (toll-free), e-mail address, and website with contact information and/or a contact form for the IAS Provider.

To the extent Signatory is already required by Applicable Law to notify an Individual of an incident that would also be a TEFCA Security Incident, this section does not require duplicative notification to that Individual.

### Revised IAS Provider Security Requirements (Contd.)

 Blue background text is new. Red background text was removed. Green text was moved.
 10.5 Additional Security Requirements for IAS Providers. This Section 10.5 shall apply to

Version 2.0 text:

- Additional Security Requirements for IAS Providers. This Section 10.5 shall apply to Signatory if Signatory is an IAS Provider.
  - 10.5.1 Scope of Security Requirements. An IAS Provider must meet the applicable security requirements set forth in Section 12 for all Individually Identifiable Information it maintains as an IAS Provider, regardless of whether such information is TI.
  - 10.5.2 IAS Incident Notice to Affected Individuals. If an IAS Provider reasonably believes that an Individual has been affected by an IAS Incident, it must provide such Individual with notification without unreasonable delay and in no case later than sixty (60) days following Discovery of the IAS Incident. The notification required under this Section 10.5.2 must be written in plain language and shall include, to the extent possible, the information set forth in the applicable SOP(s). To the extent Signatory is already required by Applicable Law to notify an Individual of an incident that would also be an

IAS Incident, this Section 10.5.2 does not require duplicative notification to that Individual.

### Revised IAS Provider Security Requirements (Contd.)

- Blue background text is new. Red background text was removed. Green text was moved.
- Version 2.0 text:
- Section 10.7 was removed
- 10.7. Provisions that Apply to Subcontractors and Agents of IAS Providers (Required Flow-Down). To the extent that Signatory is an IAS Provider and uses subcontractors or agents with respect to the provision of such Individual Access Services, it shall include in a written agreement with each such subcontractor or agent a requirement to comply with the following:
  - To act in accordance with each of the applicable consents required of Signatory under Section 10.2;
  - To act in accordance with each of Signatory's applicable Written Privacy and Security Notices pursuant to Section 10.3;

(iii) To act in accordance with Section 10.4 when directed to do so by Signatory;

### **Revised Annual Security Assessments Text**

#### OLD (Top Left)

#### NEW (Bottom Right)

- 12.1.3. <u>Annual Security Assessments.</u>Signatory must obtain a third-party security assessment and technical audit no less often than annually and as further described in the applicable SOP. Signatory must also provide evidence of compliance with this section and, if applicable, of appropriate mitigation efforts in response to the findings of the security assessment and/or technical audit within thirty (30) days to the RCE as specified in the SOP.
  - 12.1.3 <u>Annual Security Assessments</u>. Signatory must obtain a third-party security assessment and technical audit no less often than annually and as further described in the applicable SOP. Within thirty (30) days of completing such annual security assessment or technical audit, Signatory must provide evidence of completion and mitigation as specified in the applicable SOP.

### eHealth Exchange TEFCA Security Incident Protocol

#### Source:

https://ehealthexchange.org/wpcontent/uploads/2023/12/20231205 -eHealth-Exchange-TEFCA-Security-Incident-Protocol.pdf Effective Date: 12/5/2023 Last Revision Date: NA QHIN Governance Committee Approval Date: 11/2/2023

8300 Boone Blvd., Suite 500, Vienna, Virginia, 22182

eHealth Exchange

#### EHEALTH EXCHANGE TEFCA SECURITY INCIDENT PROTOCOL

#### Scope and Authority

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, has established the QGC as a standing subcommittee with the authority specified in the Onboarding and Designation SOP, the eHealth Exchange QHIN TEFCA Terms and Conditions and this Protocol.

In accordance with eHealth Exchange Operating Policy & Procedures (OPP) #10 (Participant Opt-Out of New Data Sharing Agreements), this protocol applies to all Participants that do not opt-out of the eHealth Exchange QHIN and are thus bound by the TEFCA Terms and Conditions.

#### Purpose

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.

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.



### New Encryption Requirement

- Next text in section 12.4
  - 12.4 <u>Encryption</u>. If Signatory is a NHE (but not to the extent that it is a federal agency or any other type of entity exempted from compliance with this Section 12.4 in an applicable SOP), Signatory must encrypt all Individually Identifiable Information it maintains, both in transit and at rest, regardless of whether such information is TI. Requirements for encryption may be set forth in an SOP.

#### • From the TEFCA Glossary:

**Non-HIPAA Entity (NHE)**: a QHIN, Participant, or Subparticipant that is neither a Covered Entity nor a Business Associate under HIPAA with regard to activities under the Framework Agreement. *Source: Common Agreement Version 2* 

Source: https://rce.sequoiaproject.org/wp-content/uploads/2024/01/Draft-TEFCA-Glossary-508-Compliant.pdf

### New Termination Technical Control Requirement

#### 17.3.5 Effect of Termination of the Common Agreement.

(i) Upon termination of this Common Agreement for any reason, RCE shall promptly remove Signatory and its Participants and Subparticipants from the RCE Directory Service and any other lists of QHINs that RCE maintains. Signatory shall implement the technical mechanism(s) necessary to ensure that its Participants' and Subparticipants' ability to participate in TEFCA Exchange is terminated upon termination of this Common Agreement.

#### New Suspension Technical Control Requirement

17.4.4 Effect of Suspension. The suspension of Signatory's ability to participate in TEFCA Exchange pursuant to this Section 17.4 has no effect on Signatory's other obligations hereunder, including, without limitation, obligations with respect to privacy and security. During any suspension pursuant to this Section 17.4, Signatory's inability to exchange information under this Common Agreement or comply with those terms of this Common Agreement that require information exchange shall not be deemed a breach of this Common Agreement. In the event of suspension of Signatory's ability to participate in TEFCA Exchange, Signatory shall communicate to its Participants, and require that they communicate to their Subparticipants, that all TEFCA Exchange by or on behalf of Signatory's Participants and Subparticipants will also be suspended during any period of Signatory's suspension. Signatory is responsible for having and implementing the technical mechanism(s) necessary to ensure that its Participants' and Subparticipants' ability to participate in TEFCA Exchange is suspended during the period of Signatory's suspension from TEFCA Exchange.



### New Exhibit 1 Technical Considerations

**Breach of Unencrypted Individually Identifiable Information**: the acquisition, access, or Disclosure of unencrypted Individually Identifiable Information maintained by an IAS Provider that compromises the security or privacy of the unencrypted Individually Identifiable Information.

**Directory Entry(ies)**: listing of each Node controlled by a QHIN, Participant or Subparticipant, which includes the endpoint resource for such Node(s) and any other organizational or technical information required by the QTF or an applicable SOP.

**Exchange Purpose or XP:** means the reason, as authorized by a Framework Agreement, including the applicable SOP(s), for a transmission, Query, Use, Disclosure, or Response transacted through TEFCA Exchange.

### New Exhibit 1 Technical Considerations (Contd.)

XP Code: the code used to identify the XP in any given transaction, as set forth in the applicable SOP(s).

8.1 <u>Security Controls</u>. You shall implement and maintain appropriate security controls for Individually Identifiable Information that are commensurate with risks to the confidentiality, integrity, and/or availability of the Individually Identifiable Information. If You are a NHE, You shall comply with the HIPAA Security Rule provisions with respect to all Individually Identifiable Information as if such information were Protected Health Information and You were a Covered Entity or Business Associate. You shall comply with any additional security requirements that may be set forth in an SOP applicable to Participants and Subparticipants.

### Current eHealth Exchange Protocols

- Source:
- <u>https://ehealthexchange.org/what-we-do/tefca-and-ehealth-exchange/</u>



View Resources -			
۵	eHealth Exchange TEFCA Terms and Conditions		
D	Change Management Protocol		
۵	Dispute Resolution Protocol		
۵	Enforcement Protocol		
D	Governance Protocol		
D	Operations and Reporting Protocol		
D	Security Incident Protocol		
۵	Validation Plan (See Attachment #3 for details)		
D	TEFCA SOPs		
۵	Participant Subparticipant QHIN Quarterly Report		

# **Q&A/Open Discussion**

eHealth Exchange

## For More Information



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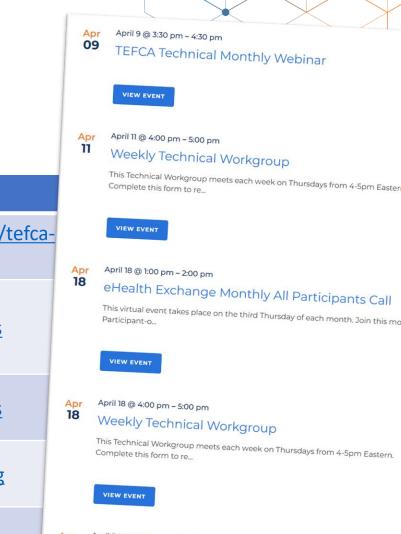


### **Readiness Checklist Directory & Reporting**

- https://ehealthexchange.org/what-we-do/tefca-and-ehealth-exchange/
- Interactive walkthrough of full checklist

Readiness Checklist for Connectivity to the Trusted Exchange Framework (TEFCA) via eHealth Exchange (Vers **Diverview**: While the eHealth Exchange Hub will address many of the new TEFCA requirements on its Participants' behalf, the requirements below represent Trusted Exchange Framework (TEFCA) requirements Exchange Framework via eHealth Exchange must satisfy not only existing eHealth Exchange requirements, but also all of the supplemental TEFCA requirements below. The requirements below may replace, cha This is a living document: As the Recognized Coordinating Entity (RCE) and Office of the National Coordinator (ONC) publish and revise artifacts at https://rce.sequoiaproject.org/tefca-and-rce-resources, this ch Nudience: Potential eHealth Exchange QHIN Participants seeking to understand the eHealth Exchange QHIN's Participant TEFCA requirements. The reader should have a basic knowledge of eHealth Exchange, ubsequently discuss with you your plans to connect to the Trusted Exchange Framework. General Operational Concept: The eHealth Exchange QHIN Hub acts as a bi-directional TEF gateway for eHealth Exchange Participants that don't opt-out of eHealth Exchange TEFCA exchange. The eHealth Exchange the instance of the effect of the **EF** = Trusted Exchange Framework, the structure consisting of QHIN-to-QHIN health data exchanges, established by the TEFCA legal agreement, SOPs, and technical specifications. equirements flow down to Participants, and their Sub-Participants. Health Exchange QHIN Hub = A unique instance of the eHealth Exchange Hub technology facilitating TEFCA transactions. Citations/Links Additional Considerations \* Reference & Service Specification Requirements https://www.healthit.

### How might I obtain additional information?



#### April 24 @ 9:00 am - 9:30 am TEFCA Office Hours

This webinar is for eHealth Exchange participants to ask any questions related to TEFCA and eHealth  $\ldots$ 

VIEW EVENT

How	When	Where	
<ol> <li>Visit eHealth</li> <li>Exchange Web Site</li> </ol>	Any time	https://ehealthexchange.org/what-we-do/tefca and-ehealth-exchange	- Apr 18
<ol> <li>Monthly</li> <li>Participant Web</li> <li>Meetings</li> </ol>	Typically, the 3rd Thursday of Each Month at 1 pm ET	https://ehealthexchange.org/events	18
3. Monthly TEFCA Technical Call	See web site	https://ehealthexchange.org/events	Apr 18
4. Email	Any time if you have a specific question	administrator@ehealthexchange.org	
5. Monthly TEFCA Office Hours (Q&A)	See web site	https://ehealthexchange.org/events	Apr 24

### Major Technical Differences eHealth Exchange QHIN Participants Must Support

- Adopt USDCI v1 data classes and elements
- Adhere to Project US@ patient addressing
- Adopt IHE ITI Technical Framework Revisions 17.0 (versus Revision 8.0)
- Accept aggregated XCPD responses
- New PurposeOfUse values
- Various requirements such different consent attribute structure, subparticipant directory entries and detailed reporting, onboarding log submissions, specific test patients, and quarterly reporting.

#### Next Steps

Review the published policy documents (not discussed today)
 Review the TEFCA Readiness Checklist
 Let the eHealth Exchange staff know of your organization's intentions (if you haven't already)

#### email: <a href="mailto:administrator@ehealthexchange.org">administrator@ehealthexchange.org</a>