January 17, 2023

RCE Monthly Informational Call

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Johnathan Coleman, RCE CISO
Alan Swenson, Executive Director, Carequality
Chantal Worzala, Principal, Alazro Consulting
Didi Davis, VP, Conformance, Testing & Interoperability
Lisa Moon, CEO, Advocate Consulting
Lindsey Elkind, Chief Legal Counsel, The Sequoia Project
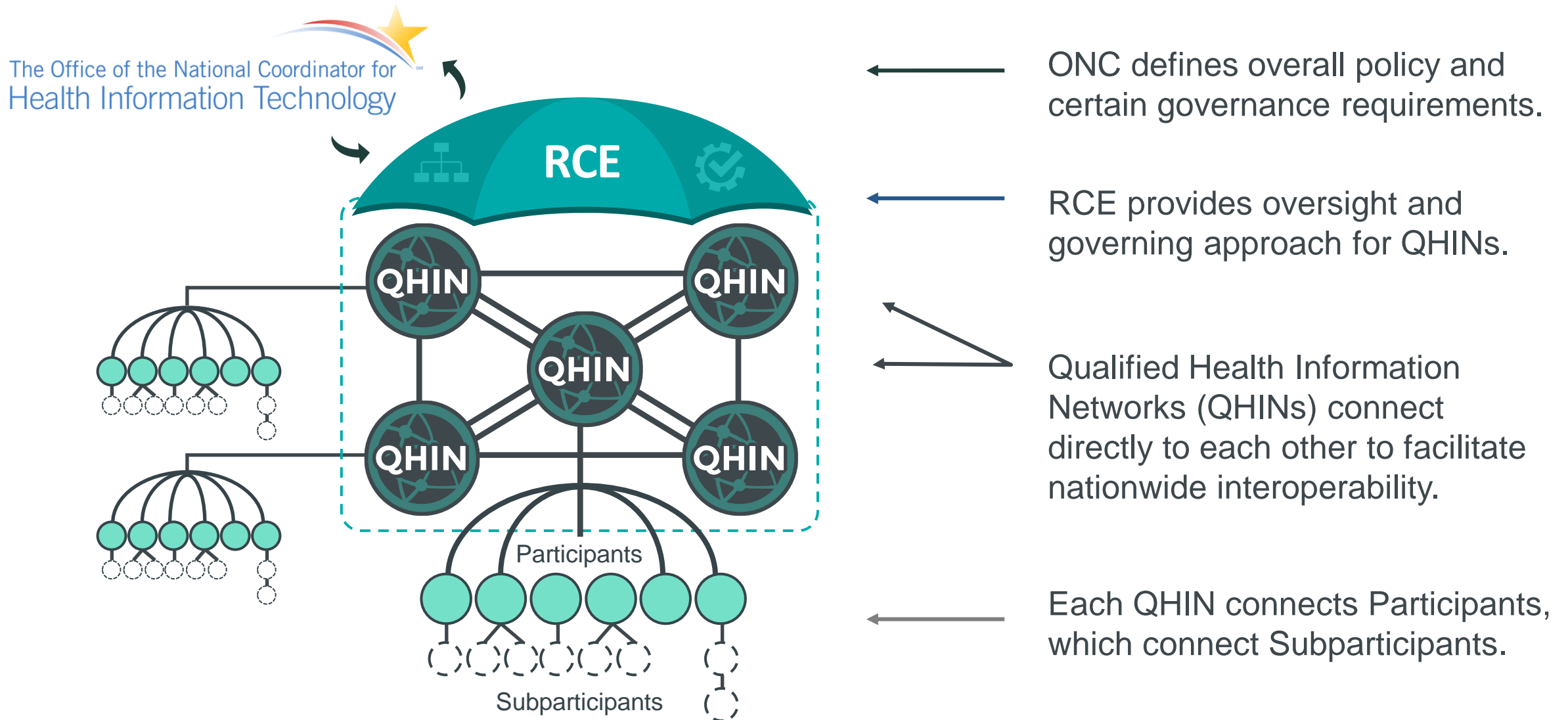Debbie Condrey, COO/CIO, The Sequoia Project

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Agenda

- How will Exchange Work under TEFCA?
- What are TEFCA Components?
- TEFCA Facilitated FHIR Implementation Guide – Pilot Version
- Revised Onboarding & Designation SOP and Application – Stakeholder Feedback
- Draft QHIN, Participant, and Subparticipant Additional Security Requirements SOP – Stakeholder Feedback
- Future Use Cases
  - » Payment and Health Care Operations
  - » Public Health
- Questions & Answers

ONC defines overall policy and certain governance requirements.

RCE provides oversight and governing approach for QHINs.

Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

Each QHIN connects Participants, which connect Subparticipants.

TEFCA Components

Trusted Exchange Framework

Common Agreement

Standard Operating Procedures

QHIN Technical Framework

QHIN Onboarding

Metrics

Governing Approach

Timeline to Operationalize TEFCA

2021
- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q3/Q4 2022
- Finalize initial SOPs
- QHIN application review
- Prepare for TEFCA FHIR-based exchange pilot

Q3/Q4 2023
- Additional QHIN applications processed
- Establish Governing Council
- Follow change management process to iterate Common Agreement, SOPs, and QTF, including to support FHIR-based exchange

| 2021 | Q1/Q2 2022 | Q3/Q4 2022 | Q1/Q2 2023 | Q3/Q4 2023 |

Q1/Q2 of 2022
- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q1/Q2 of 2023
- Onboarding of initial QHINs
- Additional QHIN applications processed
- Establish Transitional Council
- Launch TEFCA FHIR-based exchange pilot

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Applications Can Now be Submitted!

Applications Can Now be Submitted

TEFCA Facilitated FHIR Implementation Guide

Target Milestones

- Publish draft IG for stakeholder feedback – Oct 2022
- Publish revised IG for pilot purposes – Dec 2022
- Facilitate connectathon-style testing event(s) as pilot – Feb-Mar 2023
- Publish Final FHIR IG – April 2023

Facilitated FHIR IG Feedback

- The RCE collected feedback on the draft TEFCA Facilitated FHIR Implementation Guide from October 7 through November 7.
- 17 Companies and Individuals submitted Feedback through the form and via emailed submissions
- 130 total comments were received
- Detailed feedback on certificate management was received that will have long ranging impact
- Many were able to give valuable insight into the technical aspects of authentication and authorization flows
- Details on the general requirements will give needed clarity.

- Defined Provenance requirements
- Clarified QHIN Patient Discovery returns an unqualified endpoint
  - » not specific to the patient context
- Clarified certificates SHALL support RS256, and SHOULD support ES256, ES384 and RS384. All X.509 certificates SHALL have RS256 keys and SHOULD have ES256, ES384 and RS384 keys
- Allowed for organizations, not just individuals, to be a patient representative

Pilot Assumptions

Objective:
- To demonstrate readiness of FHIR exchange for operational deployment at scale
  - » Road test the IG by a representative group of HINs, providers, payers and IAS providers
  - » Demonstrate Client Dynamic Registration using UDAP

Approach
- Publish draft IG with 60-day stakeholder feedback period
- In parallel, provide for a short development window for "pilot" participants
- Facilitate connectathon style testing event involving test systems, dummy patient data for defined use case(s) / workflows, end to end
- Possibly facilitate additional connectathon style event open to all (under consideration)
- Publish final IG for adoption

NOTE:
- There will not be any designated QHINs for this process; pilot participants may or may not qualify as QHINs/QHIN Participants
- As a new HL7 standard, there may be a lag in deploying UDAP to FHIR architecture

Updates to QHIN Onboarding & Designation SOP and QHIN Application

Eligibility for Subsidiaries

Current SOP	Proposed Update
• Signatory must meet Eligibility Criteria as its own legal entity	• Wholly-owned subsidiaries are able to inherit certain characteristics, experience, or qualifications from their parent entity. For example, 12-months of query experience or audited financials.

Role of the Designated Network Governance Body

Current SOP	Proposed Update
• DNGB must have responsibility, oversight, and control, including final-decision making authority over the Governance Functions	• Clarifying the minimum role of the DNGB in each of the identified Governance Functions » Technical Framework » Dispute Resolution » Data Breach Response and Management » Enforcement of Participant Compliance » Change Management

Quorum Requirement

Current SOP	Proposed Update
• Participant and Subparticipant representatives must have voting power, **must be able to constitute a quorum of the Designated Network Governance Body (DNGB)**, and must represent the diversity of Participants and Subparticipants in the Signatory's Designated Network.	• Retain the quorum requirement but clarify that QHINs may require QHIN staff/non-voting members at any DNGB meeting

Dispute Resolution

Current SOP

- Signatory must provide a detailed description of the dispute resolution process that may arise among the Signatory and a Participant or among Participants with respect to the exchange of information via the Designated Network

Proposed Update

- Clarify that the dispute resolution process must address the following types of disputes:

  » Participant/Participant (or Subparticipant)
  » Participant/QHIN
  » QHIN/QHIN (participation in the TEFCA QHIN/QHIN dispute resolution process)

Reporting of Historic Disputes

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Current SOP

- Signatory shall provide a detailed description of such dispute resolution process and: (1) all disputes that have been processed through the dispute resolution process during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application; (2) any disputes that are pending at the time Signatory submits its application; and (3) any legal claims filed during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application that arose out of a dispute that was first brought to Signatory's dispute resolution process or that was permitted to bypass such process (e.g., a petition for injunctive relief), to the extent Signatory knows of any such legal claims. Signatory must provide the information for (1) – (3) for any Health Information Network operated by Signatory (4.g.ii)

Proposed Update

- Replace current reporting requirements and only require applicants to disclose the following:

  » if they are currently suspended from another network or are suspended at any time during onboarding process

  » if there was a dispute, incident, complaint or allegation that resulted in termination from another network for cause [in last 24 months or at any time during onboarding process]

  » if they voluntarily suspended or terminated participation in another network

Draft QHIN, Participant, and Subparticipant Additional Security Requirements SOP

Future Use Cases: Public Health

Public Health Exchange SOP

- Collect stakeholder input to inform the first version of the TEFCA Public Health Exchange Purpose Implementation SOP to be published by mid 2023

- Timeline

Date	Activity	Purpose
Dec 2022 – Jan 2023	1:1 PH SME Interviews	Gather Information & Input
Jan 2023 – March 2023	PH Stakeholder Feedback Meetings	Gather Feedback & Develop PH SOP
May 2023	Publish PH SOP for Stakeholder Comment	Refine & Make Final Edits

Resources

- Common Agreement v. 1
- QHIN Technical Framework
- FHIR® Roadmap for TEFCA
- Standard Operating Procedures
- QHIN Application
- Communication Protocols
- User's Guide
- Benefits of TEFCA by Stakeholder Factsheets
- FAQs

https://rce.sequoiaproject.org/tefca-and-rce-resources/

Additional Resources:
https://www.healthit.gov/tefca

All Events Registration and Recordings: https://rce.sequoiaproject.org/community-engagement/

Upcoming Monthly Informational Call:
Tuesday, February 21 | 12:00 – 1:00 p.m. ET

Questions & Answers

For more information:
rce.sequoiaproject.org