TEFCA: THE COMMON AGREEMENT

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Agenda

Overview of the Common Agreement

What's coming from the RCE…

Answering your questions: open Q&A

Reminder: This presentation is informational only and does not constitute legal advice. Organizations should consult with their attorney for legal advice regarding how the Common Agreement may apply to them

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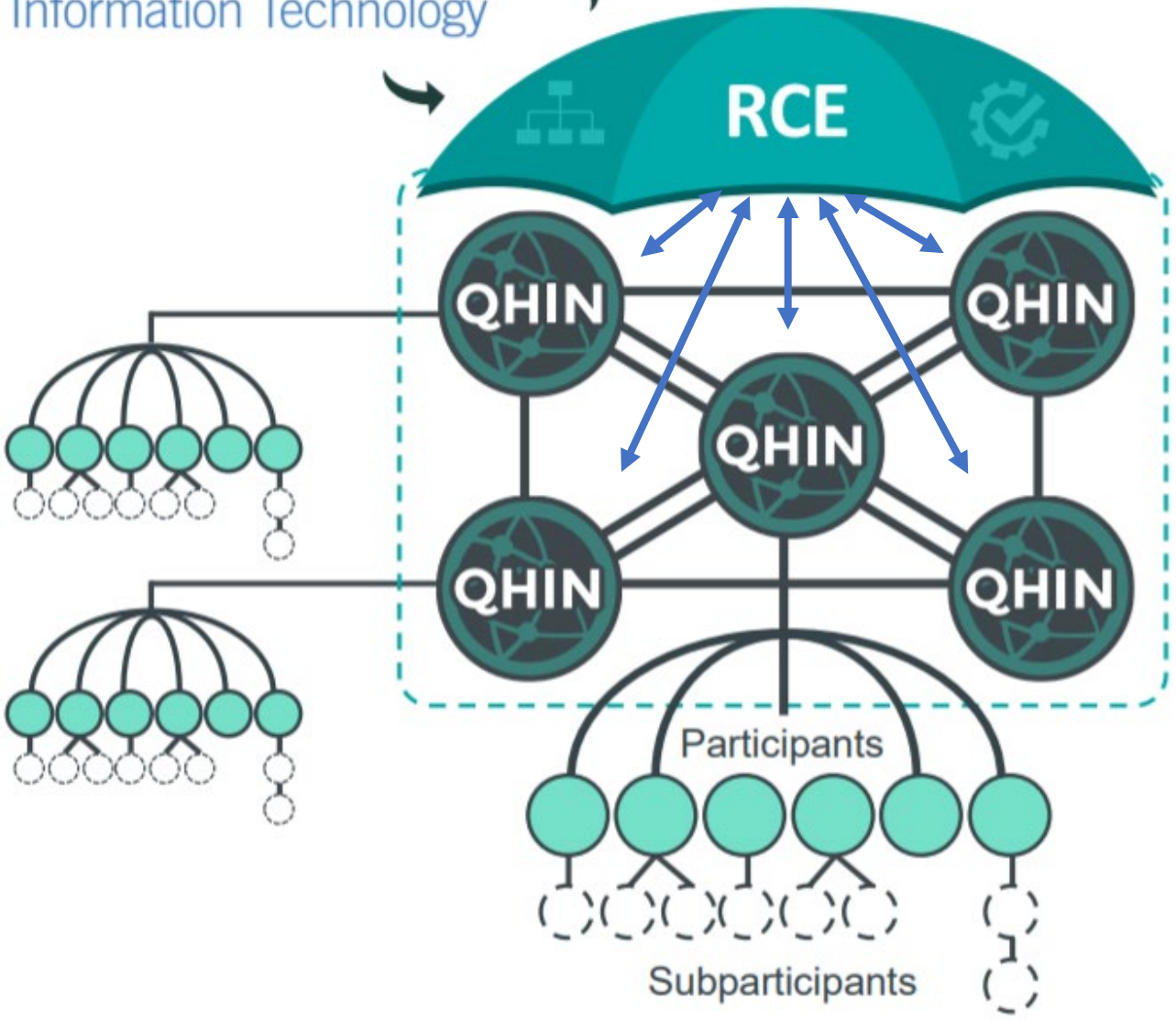
The Office of the National Coordinator for Health Information Technology

TEFCA Ecosystem



The **Common Agreement** is the binding agreement between the RCE and a "signatory" (prospective QHIN / QHINs)

- Incorporates by refence QTF & SOPs

QHINs appear to be implied third party beneficiaries of the Common Agreement (see Sections 1.2.1 and 7.2.3)

The Common Agreement also requires QHINs to **flow down more than 30+ provisions** to Participants and Subparticipants

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Section 7. Confidentiality and Accountability

Section 8. RCE Directory

Section 9. TEFCA Exchange Activities

Section 10. Individual Access Services (Required Flow-Downs, if Offering Individual Access Services)

Section 11. Privacy

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Section 13. General Obligations

Section 14. Specific QHIN Obligations

Section 15. Dispute Resolution

Section 16. Stability of the QHIN Network

Section 17. Fees

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Ten Key Features

1. QHINs: Eligibility and Ongoing Requirements (§§ 4, 14 and 16)
2. Race to be First: RCE Directory (§ 8)
3. Participants and Subparticipants: Flow-Downs (Throughout)
4. Governance and Change Management (§§ 3 and 5)
5. Cooperation and Non-Discrimination (§ 6)
6. Exchange Purposes and Downstream Uses (§ 9)
7. Individual Access Services (IAS) and IAS Providers (§§ 9 and 10)
8. Privacy and Security Requirements (§§ 11 and 12)
9. RCE Fee Schedule and QHIN Fees (§ 17)
10. Other Important Business Terms (§§ 7, 13, 15 and 18)

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QHINs: Eligibility and Ongoing Requirements (§§ 4, 14 and 16)

- **Corporate Status:** signatory must be a U.S. entity (cannot be owned/controlled by non-U.S. person or entity)
- **Exchange Content:** must be able to exchange all electronic information that would be ePHI (except HIPAA Psychotherapy Notes and civil/criminal/administrative actions) – called "Required Information"
- **Exchange Manner:** must demonstrate can meet all required functions, including QTF (12-month query functionality)
- **Legal & Governing Infrastructure:** *at the time of application* must have this in place
- **Resources:** *at the time of application* must demonstrate technical and financial resources

SOP for QHIN eligibility has not been released as of the date of this webinar.

Race to be First: RCE Directory (§ 8)

- QHINs, Participants and Subparticipants **must** use the **RCE Directory Service** (key to connectivity of the network)
- Before listing **any entity** as a Participant or Subparticipant in the RCE Directory under a QHIN, that QHIN must confirm that the Participant or Subparticipant is not already listed under another QHIN
- **No duplicative entries are allowed**
- Participants and Subparticipants are free to change their QHIN, but may only use one QHIN

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Participants and Subparticipants: Flow-Downs (Throughout)

RCE specifically identified required flow-downs:

6.1 Cooperation

6.2.1 Prohibition Against Exclusivity

6.2.2 No Discriminatory Limits on Exchange of TEFCA Information

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 Services: 7 Sub-Flow-Downs

11.1 Compliance with the HIPAA Privacy Rule: 11 Sub-Flow-Downs

12.1.4 Participants and Subparticipants: security requirements

12.2 TEFCA Information 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

There are other provisions in the Common Agreement that are not designated as required flow-downs, but still require flow-down to Participants and Subparticipants. For example, Section 14.2 requires QHINs to flow down compliance with applicable SOPs to Participants. SOPs should state scope of applicability

Governance and Change Management for Common Agreement (§§ 3 and 5)

- **Transitional Council (TC):** up to 10 QHIN representatives; first year only
- **Governance Council (GC):** 21 members from QHIN Caucus and Participant/Subparticipant Caucus
- **TC/GC Role:** review amendments to Common Agreement, QTF, and SOPs; participate in development of SOPs and strategic roadmap; resource to the RCE; oversight for dispute resolution; and TEFCA advocate
- **QHIN Caucus:** 2/3 vote needed to approve amendments (1 vote per QHIN), unless RCE determines needed to comply with applicable law
  - Different voting process used for SOP changes (*e.g.*, 2/3 vote of QHIN Caucus and 2/3 Participant/Subparticipant Caucus – once established)
- **ONC:** ONC must approve all changes, additions, and deletions
  - EXCEPT it seems the RCE has sole authority over the RCE fee schedule (Schedule 1 is exempt from the Change Management provision)

Please see the SOPs for the Transitional Council and TEFCA Governing Council for more details, available here

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Cooperation and Non-Discrimination (§ 6)

QHINs, Participants and Subparticipants all expected to:

- Timely respond to inquiries
- Resolve issues before pursuing formal dispute resolution
- Make reasonable efforts to notify the RCE and other QHINs of persistent and widespread connectivity failures
- Share information regarding cyber security
- **NOT LIMIT INTEROPERABILITY WITH OTHERS** (broad prohibition)
  - CANNOT require exclusivity with respect to other services concurrently with its TEFCA agreements
  - CANNOT treat similarly situated individuals/entities differently

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Exchange Purposes and Downstream Uses (§ 9)

Permitted and **Mandatory** Exchange Purposes:

- **Treatment** (as defined by HIPAA)
- Payment (as defined by HIPAA)
- Health Care Operations (as defined by HIPAA)
- Public Health (as described by HIPAA)
- Government Benefits Determinations (for governmental agencies to make non-health benefits determinations)
- **Individual Access Services** (*e.g.*, for consumer facing applications to assist individuals in obtaining access)
- Any other purpose in a SOP

Limited by the requirements of applicable law, Common Agreement and SOPs. SOPs will set forth mandatory exchange purposes

There are no restrictions on downstream uses or redisclosures of exchanged data

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Individual Access Services (IAS) and IAS Providers (§§ 9 and 10)

IAS = giving an individual—who has a direct relationship with a QHIN, Participant, or Subparticipant—the ability to access the individual's health information. **COMMON AGREEMENT SOP EXPECTED TO REQUIRE RESPONSES TO AN IAS QUERY**

IAS Provider = a QHIN, Participant or Subparticipant that offers IAS. **COMMON AGREEMENT DOES NOT REQUIRE ANYONE TO BE AN IAS PROVIDER.** IAS providers must meet notice, security, consent, data deletion, data potability and subcontracting requirements

THERE ARE NO SPECIFIC INDIVIDUAL IDENTITY OR AUTHORITY VERIFICATION REQUIREMENTS FOR IAS PROVIDERS

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Privacy and Security Requirements (§§ 11 and 12)

- **Everyone** exchanging data in the TEFCA ecosystem (including non-HIPAA entities) must comply with certain HIPAA Privacy Rule requirements and HIPAA Security Rule requirements (more detail expected in SOPs)
- **QHINs** must also obtain third party certification (like HITRUST); perform annual security assessments; have a Chief Information Security Officer (CISO); make security resources available to its Participants; and have cyber risk and tech errors insurance coverage (see SOP)
- **QHINs, Participants and Subparticipants** must report TEFCA Security Incidents within 5 business days and evaluate risks of uses/disclosure of TEFCA Information outside the United States

Privacy, security and breach reporting obligations are ***in addition to*** any requirements under applicable law, but do not require duplicative reporting

RCE Fee Schedule and QHIN Fees (§ 17)

- RCE will charge fees in the future – Schedule 1 (90 days notice)
  - Schedule 1 is not subject to the Change Management process (*e.g.*, voting and approval)
  - Anticipate fees for application, annual participation and ongoing testing fees
  - Possible fees for application preparation services and educational sessions
- QHINs cannot charge other QHINs fees
- Silent on how QHINs, Participants and Subparticipants finance their own internal networks

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Other Important Business Terms (§§ 7, 13, 15 and 18)

- **Responsibility:** Signatories responsible for harms to the RCE and other QHINs to the extent caused by the signatory's breach of Common Agreement or SOPs (not applicable to government agencies); RCE (TC, GC, Causes, *etc.*) released from liability, except for direct harm caused by RCE breach
- **Monetary Cap:** RCE/QHIN liability capped at $2mil per occurrence /$5mil aggregate (not applicable to government agencies)
- **Dispute Resolution:** non-binding process and RCE has no power to impose monetary damages
- **Governing Law and Venue:** court within 25 miles of Alexandria, Virginia and subject to applicable laws' conflict of law provisions

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What's coming from the RCE…

- Webinars (subscribe to RCE feed for most recent updates)
- More SOPs (current SOPs available here)
  - Onboarding & Designation
  - Required Information
  - Treatment (Required Exchange Purpose)
  - IAS (Required Exchange Purpose)
- Flow Down Provision Summary for Participants / Subparticipants
- Possibly NIST Individual Assurance Level 2 (IAS2) for IAS

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Q & A

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