Trusted Exchange Framework and Common Agreement -
Additional Required Terms and Conditions:

*Operation of Exchange Activities*

Webinar, Part 1: February 18 & 19, 2020
Webinar, Part 2: February 26, 2020
This project is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under 90AX0026/01-00 Trusted Exchange Framework and Common Agreement (TEFCA) Recognized Coordinating Entity (RCE) Cooperative Agreement for $900,000. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.
How To Participate Today

Problems or Questions? Contact the RCE Team at:

rce@sequoiaproject.org
Agenda

• Welcome
• Purpose
  – 2/18 and 2/19: Operation of Exchange Activities (Part 1)
    • Allocation of liability
    • QHIN confidential business information
  – 2/26: Operation of Exchange Activities (Part 2)
    • Duty to cooperate
    • Dispute resolution process
  – 3/4: Preserving the Stability of the Network
  – 3/16: Governance of Exchange Activities
Meet the RCE Team

Mariann Yeager
CEO
The Sequoia Project

Steve Gravely
Founder & CEO
Gravely Group

Dave Cassel
Executive Director
Carequality Inc.

Chantal Worzala
Principal, Alazro Consulting

Mark Segal
Principal, Digital Health Partners

Stephanie Rizk
Manager, Health IT Policy
RTI International
What is The Common Agreement?

The **Common Agreement** will provide the governance necessary to scale a functioning system of connected HINs that will grow over time to meet the demands of individuals, clinicians, and payers.

The Common Agreement will be a legal document that QHINs sign. Some provisions of the Common Agreement will flow down to other entities (including providers) via contracts.

**Stakeholders will be able to comment on the draft Common Agreement.**
Draft Minimum Required Terms and Conditions (MRTCs)

Published April 2019 for Public Comment

1. Definitions
2. Initial application, onboarding, designation and operation of QHINs
3. Data quality and minimum necessary
4. Transparency (e.g. agreements, fee schedules, disclosures)
5. Cooperation and non-discrimination
6. Privacy, security and patient safety
7. Participant minimum obligations
8. Participant member minimum obligations
9. Individual rights and obligations

ONC developed with input from public comments and RCE
DRAFT Additional Required Terms and Conditions (ARTCs)

• Additional necessary terms for an effective, operational data sharing agreement
• Generally applies to QHINs with some flow-down provisions
• May not conflict with MRTCs

RCE to develop Common Agreement for approval by ONC and release for public comment
ARTC Framework

Categories of important functions that are not addressed by the MRTCs

- Operation of the exchange activities under the Common Agreement
- Stability of the QHIN network
- Governance of the exchange activities under the Common Agreement
- *Contract Administration*
ARTCs: Operation of Exchange Activities under the Common Agreement

- Compliance with Standard Operating Procedures
- Application Process and Onboarding
- **Accountability**
  - Harm to RCE / Other Signatories
  - RCE Accountability
  - Limitation on Liability
- QHIN and RCE Confidentiality
- Cooperation
- Dispute Resolution
- Fees
ARTC – Operation of Exchange Activities (Part 1)
February 18 & 19, 2020
ARTCs: Operation of Exchange Activities under the Common Agreement

• Compliance with Standard Operating Procedures
• Application Process and Onboarding
• **Accountability**
  – Harm to RCE / Other Signatories
  – RCE Accountability
  – Limitation on Liability
• **QHIN and RCE Confidentiality**
• Cooperation
• Dispute Resolution
• Fees
Proposed ARTC: QHIN Accountability

• General Principle: QHINs are responsible for their own actions and not for the actions of other QHINs or their Participants or Participant Members

• Time-honored principle that liability rests with the party that caused the liability

• Legal standard is breach of the Common Agreement or a Standard Operating Procedure
  – Considered a higher standard, such as gross negligence, but that seems too high a bar

• Exception: Some QHINs, like governmental agencies, may be prohibited by law from being held liable and this is recognized
Proposed ARTC: RCE Accountability

• The RCE is operating under a Cooperative Agreement with ONC to develop the Common Agreement, QHIN Technical Framework and Standard Operating Procedures as well as govern the exchange activities.
• RCE would be liable for direct damages that a QHIN suffers from a breach of the Common Agreement by the RCE.
• Only the RCE is liable, not the RCE board members, committee members, employees or contractors.
Proposed ARTC: Shared Liability

• Multi-party data exchange is complicated, and harm may be caused by more than one party
• If a QHIN is being held liable but believes that others may have contributed to the harm, a QHIN can petition the RCE to work with it to identify the other QHINs, or their Participants or Participant Members, that it thinks contributed to the harm
• QHIN must work in good faith with the RCE to identify others that contributed to the damages
• Parties agree to work cooperatively with each other to address issues related to the exchange activities under the Common Agreement
• If a satisfactory allocation of liability cannot be achieved, the matter must go to the Dispute Resolution process
Discussion: Limitations of Liability

- Concerns about liability often cited as reasons that organizations do not participate in data sharing networks.
- We are seeking a balance between allowing QHINs to recover money damages if they suffer harm and not asking QHINs to take on unlimited liability.
- Proposing a liability cap of $3M.
- Exception: If a QHIN is legally prohibited from limiting its right to recover damages, such as federal agencies, this liability cap will not apply to either the QHIN or the RCE.
Summary of Questions and Comments from 2/18/2020

• There were numerous questions regarding who would face liability within the TEFCA ecosystem (RCE, QHIN, Participant/Participant Member) and under what circumstances.
  – Various questions regarding government liability in TEFCA as it relates to sovereign immunity.
  – Shared liability in context of QHIN responsibilities in reporting Participant/Participant Member actions.
  – Feasibility of adding an inflation clause to the proposed liability cap.
• There were additional questions on existing international models of liability and real-world examples of the type of harm that can be considered liabilities for any party.
Proposed ARTC: Confidential Information

• **General Principle** - QHIN and RCE agree to use the other Party’s Confidential Information *only* as authorized in the Common Agreement (CA)

• Limit disclosures only to employees and agents who require such knowledge and use it in the ordinary course and scope of their employment or retention

• Employers and agents must protect Confidential Information in a manner substantially equivalent to the CA terms

• Limits use of QHIN directory to supporting operational activities under the Common Agreement
ARTCs: Operation of Exchange Activities under the Common Agreement

- Compliance with Standard Operating Procedures
- Application Process and Onboarding
- Accountability
  - Harm to RCE / Other Signatories
  - RCE Accountability
  - Limitation on Liability
- QHIN and RCE Confidentiality
- Cooperation
- Dispute Resolution
- Fees
Proposed ARTC: Duty to Cooperate with RCE and other QHINs (1)

- **General Principle**: QHINs expected to cooperate with each other and the RCE on issues related to information exchange under the Common Agreement.
- QHINs will collaboratively participate in discussions coordinated by RCE to address differing interpretations of requirements and require that their Participants and Participant Members cooperate.
- Make reasonable efforts to accommodate other QHIN schedules and reasonable operational concerns.
- Respond within three (3) business days to inquiries from the RCE or other QHINs.
- Seeking feedback on whether this time frame is reasonable?
- Not required to disclose EHI as part of your cooperation unless you are permitted to do so by Applicable Law.
Proposed ARTC: Duty to Cooperate with RCE and other QHINs (2)

- Cooperate with respect to notification, investigation and remediation of persistent and widespread connectivity failures
  - Notify RCE and other QHINs
  - Facilitate contact with other QHINs / Participants / Participant Members
  - Provide reasonable information (or direct its Participants or Participant Members to do so) to other QHINs to collaboratively resolve issues or disputes
  - Require its Participants / Participant Members to provide information and other relevant assistance

- Cooperate with respect to other QHIN/Participants/Participant Members with respect to breaches
  - Provide reasonable information (or direct its Participants or Participant Members to do so) to other QHINs to understand, contain and mitigate a breach, upon request
Proposed ARTC: Dispute Resolution Process (1)

- **General Principle**—An orderly process for addressing and resolving disputes among those who are exchanging information under the Common Agreement will result in more robust exchange and promote the long-term success of the network

- The Common Agreement will include a formal Dispute Resolution Process
  - Participation is mandatory
  - Results are non-binding on the parties. Governmental QHINs are prohibited by law from agreeing to binding arbitration

- Before submitting a Dispute to the formal Dispute Resolution Process, QHINs must:
  - Make commitment to promptly and fairly resolve disputes with the party most closely associated with the dispute
  - Require Participants / Participant Members to use best efforts to resolve disputes through informal discussions before invoking the RCE dispute resolution process
  - Facilitate informal resolution with Participants / Participant Members through cooperation before submitting to the formal RCE dispute resolution process
Proposed ARTC: Dispute Resolution Process (2)

- The RCE does not have authority to assess monetary damages against the QHIN, its Participants or Participant Members, but can impose other penalties (e.g. suspension / termination of exchange activities under the CA)
- Refusal to participate in the Dispute Resolution Process constitutes a material breach of the CA
- If the dispute is not resolved to the satisfaction of a party, they can seek legal redress in the courts
Next Steps

• Public stakeholder feedback calls regarding draft ARTCs
  – 2/26: Operation of Exchange Activities (Part 2)
  – 3/4: Preserving the Stability of the Network
  – 3/16: Governance of Exchange Activities

• Common Agreement Work Group (Apr-Jul 2020)
• Public feedback calls regarding draft QHIN Technical Framework (QTF)
• Continued stakeholder engagement
• Draft Common Agreement and QTF published for public comment
Get Engaged!

For more information:
Rce.sequoiaproject.org