

RCE Monthly Informational Call

November 16, 2021

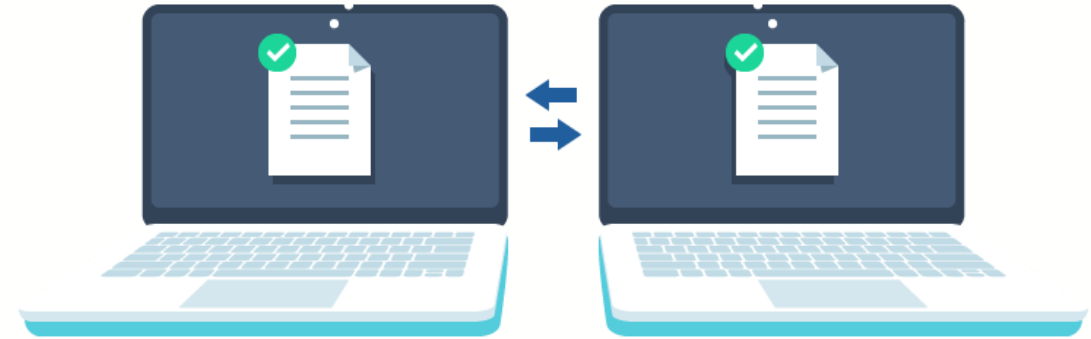


ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

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. 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.

Agenda

- Welcome and Brief Overview
- Highlight QTF Stakeholder Feedback
- Highlight Common Agreement Feedback



Meet the RCE Team



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CEO
The Sequoia Project



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TEFCA Goals



GOAL 1

Establish a floor of universal interoperability across the country



GOAL 2

Create simplified nationwide connectivity



GOAL 3

Provide the infrastructure to allow individuals to gather their data

Simplified connectivity for individuals, health care providers, health plans, public health agencies, and other stakeholders.

Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021

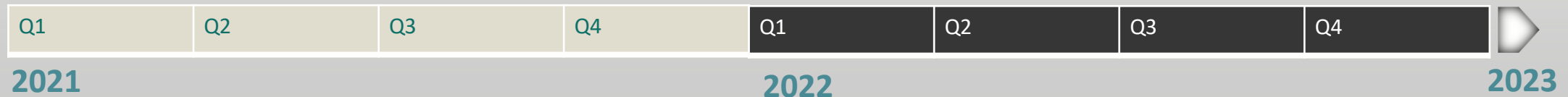
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

Calendar Q1 of 2022

- Release Final Trusted Exchange Framework, CA V1 Final, and QTF V1 Final.

During 2022

- QHINs begin signing Common Agreement.
- QHINs selected, onboarded, and begin sharing data on rolling basis.



Highlights on QHIN Technical Framework (QTF) Feedback

Feedback

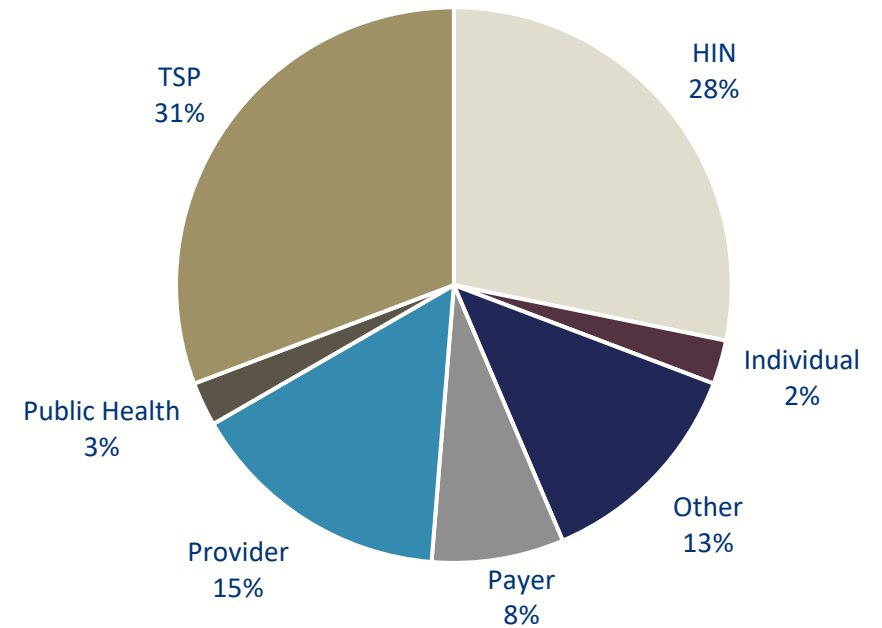
- Most comments contained small changes to wording or constraints which can be easily incorporated
- Five specific topic areas that received feedback:
 - Mandatory or Optional eMPI / RLS vs Federated Queries
 - Patient Matching Requirements
 - Document Conversion and Aggregation
 - Message Delivery
 - FHIR Roadmap

Highlights on Common Agreement Elements Feedback

Sources of Feedback

- Online feedback
- Email
- Series of Public Webinars
- Targeted Stakeholder calls
- HITAC Presentation

Health Information Networks and Technology Service Providers Represented More than Half of Formal Commenters



Feedback on Overall Approach

- Support:
 - Universal floor of interoperability
 - General alignment with HIPAA and avoidance of overlapping responsibilities for CEs/BAs
 - Support for RCE as convener to engage the community in cooperative efforts over time
 - Appreciation of extensive feedback opportunities
- Ensure approach leverages existing infrastructure
- Allow for bilateral exchange among Participants without QHINs mediating
- Need for education and outreach
 - Scenarios
 - Flow-downs requirements

Exchange Purposes

- General support for the six named Exchange Purposes
- Recommendation for phased approach or optionality
- Request for Implementation Guide for each Exchange Purpose
- Clarification on access to information by pass-through entities
- Lack of tools to segment sensitive data
- Exceptions to Responses

Participants and Subparticipants

- Clarification of the role of BAs acting on behalf of a CE
- Clarification of how a health system with multiple entities would be treated
- Need for education on what kinds of entities might fall in each category

Required Flow-Down Provisions

- Need more specificity on what they will be
- Consider developing model language for inclusion in information sharing agreements
- Need for more specificity on compliance expectations
- Need for more information on enforcement of violations

TEFCA Information and Required Information

- Requests for clarification:
 - How to operationalize definitions given broad scope (e.g., reference to all ePHI)
 - May vary by Exchange Purpose and technical capabilities
 - De-identified data
 - Non-health information
- Request to align with EHI under information blocking

Governing Approach

- Considerable agreement
- Recommendation that governing bodies be representative
- Request for clarity
 - Specific roles, authorities, etc.
 - Dispute resolution process
- Role of Governing Council in designating QHINs

QHIN Designation and Eligibility Criteria

- Support for new market entrants/innovators to be able to become QHINs
- Request for clarification re: how to “demonstrate capability” to support all exchange purposes
- Request for greater specificity regarding thresholds or benchmarks that will demonstrate that QHIN has requisite transaction volumes, financial resources, governance structure, etc.
- Concern re: engagement of non-US entities and “off-shoring” of data
 - Prohibited in many federal and state health benefits contracts (Medicare Advantage, some Medicaid)
 - Could trigger compliance obligations under non-US laws

RCE Directory Service

- General support
- Requests for more information:
 - Will there be fees for use?
 - What information will it contain and how will it be kept current?
 - Will it be accessible to entities that are not QHINs/Participants/Subparticipants?

Individual Access Services (IAS)

- Some recommend that QHINs be required to offer IAS
- Privacy expectations
- IAS Privacy Notice requirements
 - Plain language, complete information on how information will be accessed, exchanged, used and disclosed
 - Granular controls and clear instructions on how to end consent
- Individual rights to have data deleted and to obtain an electronic copy
- Identity proofing and patient matching
- Clarification that offering a patient portal is not equivalent to offering IAS

Privacy and Security

- Support for third-party security accreditation/annual security assessment for QHINs
- Support for alignment with HIPAA Security requirements for CEs/BAs and non-HIPAA entities that are Participants and Subparticipants, with some entities asking for more robust requirements for all parties engaged in exchange
- Concern re: Identity Proofing:
 - Needs more explicit attention
 - Recommendations of specific NIST guidelines for Identity (NIST SP 800-63-3 and 3A) and Identity Assurance Levels (IAL2)
 - Same standard should apply to all

Consent

- Request for additional discussion of consent
- Concern that computable consent is not yet mature
- Clarity on whether discloser or requestor should collect consent
- Hard to navigate “applicable law” from local, state, and federal levels

Fees

- General support for no fees between QHINs
 - Some disagreement
- Request for clarity on fees at other levels
- Concern that QHIN fees on Participants may not always be reasonable
 - Should not serve as a barrier to participation and exchange, particularly for certain categories of Participants with limited resources
 - Should avoid transaction-based fees

Other Concerns

- Alignment with other regulations
 - Information blocking
 - CMS programs, including interoperability rules for health plans and the Promoting Interoperability Program
- Concern regarding diversity of privacy/info sharing laws at local, state and federal levels
- Patient Matching
 - Challenging issue
 - Support for minimum performance standard and reporting by QHINs
 - Engage with industry efforts to improve matching
- Interaction with efforts to address equity issues
- Need for tight coordination across interoperability efforts, with clear transition to FHIR



Questions & Answers