

The image features a decorative graphic on the left side consisting of white and light blue lines that resemble a circuit board or data network. These lines are vertical and horizontal, with small circles at various points, creating a complex, branching pattern that extends from the top to the bottom of the frame.

# THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT- IMPLICATIONS FOR PUBLIC HEALTH

# TEFCA COMMENT PERIOD

- TEFCA draft documents available at [www.healthit.gov](http://www.healthit.gov).
- Includes draft descriptive documents, terms and conditions, and technical framework requirements.
  - **The Trusted Exchange Framework (TEF), Draft 2** — Principles designed to facilitate trust between Health Information Networks (HINs). These principles are intended to guide the development of the Common Agreement.
  - **Minimum Required Terms and Conditions (MRTCs), Draft 2** — Mandatory terms and conditions that Qualified Health Information Networks (QHINs) voluntarily agree to follow. The Common Agreement will include the MRTCs, as well as additional required terms and conditions developed by an industry-based Recognized Coordinating Entity (RCE).
  - The **QHIN Technical Framework (QTF), Draft 1** — The QTF, incorporated by reference in the Common Agreement, details the technical and functional components for exchange among QHINs.
- Comments are due June 17, 2019.
- ONC also released a Notice of Funding Opportunity to select a Recognized Coordinating Entity (RCE) to develop, update, implement, and maintain the Common Agreement and the QTF.
  - Submissions are due June 17, 2019.

# TEFCA OBJECTIVES

- Provide a single “on-ramp” to nationwide connectivity
- Enable EHI to securely follow the patient when and where it is needed
- Support nationwide scalability

# SIX PRINCIPLES OF TEFCA

- Principle 1 — Standardization: Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.
- Principle 2 — Transparency: Conduct all exchange and operations openly and transparently.
- Principle 3 — Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.
- Principle 4 — Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.
- Principle 5 – Access: Ensure that Individuals and their authorized caregivers have easy access to their EHI.
- Principle 6 — Population-Level Data: Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

# PRINCIPLE 1 — STANDARDIZATION: ADHERE TO INDUSTRY AND FEDERALLY RECOGNIZED TECHNICAL STANDARDS, POLICIES, BEST PRACTICES, AND PROCEDURES

1. Adhere to applicable standards for EHI and interoperability that have been adopted by the U.S. Department of Health & Human Services (HHS), approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA).
  - Public health implications:
    - When no standards exist?
    - Get standards in ISA.
    - Participate in standards development.
2. Implement technology in a manner that makes it easy to use and that allows others to connect to data sources, innovate, and use data to support better, more person-centered care; smarter spending; and healthier people.
  - Public health implications:
    - Improved access to data.
    - More demand for data.

# PRINCIPLE 2 — TRANSPARENCY: CONDUCT ALL EXCHANGE AND OPERATIONS OPENLY AND TRANSPARENTLY

- Make terms, conditions, and contractual agreements that govern the exchange of EHI easily and publicly available.
  - Public health implications:
    - Make documentation regarding reporting easily available.
    - Clarify what information may be shared by public health authorities.
- Specify and have all HINs agree to the uses and disclosures for exchanging EHI.
  - Public health implications
    - Different public health agencies have different requirements
    - Public health utilization of data is related to, but may be different than HIPAA
- Publish, keep current, and make publicly available the HIN's privacy practices.
- When necessary, conduct any arbitration processes with other HINs in an equitable, transparent manner.
  - Public health implications
    - May not be able to defer sovereign authority to other (private) entities.

## PRINCIPLE 3 — COOPERATION AND NON-DISCRIMINATION: COLLABORATE WITH STAKEHOLDERS ACROSS THE CONTINUUM OF CARE TO EXCHANGE EHI, EVEN WHEN A STAKEHOLDER MAY BE A BUSINESS COMPETITOR

- **Do not seek to gain competitive advantage by limiting access to individuals' EHI.**
  - HINs should not discourage or impede appropriate health information exchange with competitors. This includes **throttling the speed** with which data is exchanged purely for **competitive reasons**, limiting the data elements that are exchanged with health care organizations that may be their competitor or a competitor of one of their participants, or by requiring burdensome testing requirements designed to unfairly deter or discourage connections that do not benefit the HIN.
  - Public health implications:
    - Additional information regarding rationalizations for throttling data is important, for example capacity of an entity to respond to requests.
    - Not all data maintained by public health authorities may be provided to all requesters.
    - Public health is focused on quality data. Testing helps ensure data meets quality standards.

6/7/2019

# PRINCIPLE 4 — PRIVACY, SECURITY, AND SAFETY: EXCHANGE EHI SECURELY AND IN A MANNER THAT PROMOTES PATIENT SAFETY, ENSURES DATA INTEGRITY, AND ADHERES TO PRIVACY POLICIES

Ensure that EHI is exchanged and used in a manner that promotes safe care, including consistently and accurately matching EHI to an individual.

- Public health implications- patient matching:
  - What tool/algorithm is being used?
  - Who is using it?
  - How many iterations?

Ensure providers and organizations participating in data exchange have confidence that individuals have the opportunity to exercise meaningful choice, if and when it is needed, prior to the exchange of EHI.

- Public health implications:
  - Required data reporting cannot be excluded.
  - Clear communications.
  - Form collecting and processing.



# PRINCIPLE 5 – ACCESS: ENSURE THAT INDIVIDUALS AND THEIR AUTHORIZED CAREGIVERS HAVE EASY ACCESS TO THEIR EHI

Do not impede or put in place any unnecessary barriers to the ability of individuals to access and direct their EHI to designated third parties, and to learn how information about them has been access or disclosed.

- Public health implications:
  - Resolving identities.
  - Legally Authorized Representatives.
  - Data interpretation.
  - State laws.
  - Duration of delegation of access.
  - Examples:
    - Immunization registries.
    - State laboratories.

PRINCIPLE 6 — POPULATION-LEVEL DATA: EXCHANGE MULTIPLE RECORDS FOR A COHORT OF INDIVIDUALS AT ONE TIME IN ACCORDANCE WITH APPLICABLE LAW TO ENABLE IDENTIFICATION AND TRENDING OF DATA TO LOWER THE COST OF CARE AND IMPROVE THE HEALTH OF THE POPULATION.

**Not yet in effect.**

Enable participants to request and receive multiple patient records at one time.

- Public health implications:
  - Ability or public health to respond (data volume).
  - Ability to collect considerable data.

# TEFCA KEY TERMS

- Recognized Coordinating Entity
- Qualified Health Information Networks
- Health Information Networks
- Electronic Health Information
- Health Care Providers
- Participants
- Participant Users

# RECOGNIZED COORDINATING ENTITY (RCE)

## Industry-based entity

### Roles:

1. Develop a Common Agreement that includes the MRTCs and additional terms and conditions.
2. Convene listening sessions allow stakeholders to provide feedback to the RCE.
3. Identify and monitor QHINs that agree to sign and adopt the CA.
4. Implement a process to adjudicate QHIN noncompliance with the CA.
5. Implement a process to update the CA, as needed, for ONC approval and publication.
6. Modify and update the QHIN Technical Framework, Draft 1 to detail proposed technical components for exchange among QHINs as required by the MRTCs.
7. Propose strategies that an RCE could employ to sustain the Common Agreement

# HEALTH INFORMATION NETWORK (HIN) DEFINED

A Health Information Network (HIN) is an individual or an entity that satisfies one or both of the following:

- 1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; or
- 2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

# PARTICIPANTS, PARTICIPANT MEMBERS, AND INDIVIDUAL USERS

**Participants:** Participants may include persons/entities that have entered into a contract to participate in a QHIN. Some examples include an HIN, a public health agency, a health system, a health IT developer, or a payer.

**Participant Members:** Participant Members may include persons or entities that use the services of a Participant to send and receive electronic health information (EHI).

**Individual Users:** An Individual User represents an actual person who is the subject of the EHI, such as a patient, health plan member, or a patient representative. Individual Users may have a Direct Relationship with the QHIN, Participant, or Participant Member, depending on the structure of the QHIN to which they belong. They are not themselves considered Participants or Participant Members.

# TEFCA AS A “NETWORK OF NETWORKS”

- The TEF and the Common Agreement rely on a “network of networks” structure.
- Multiple points of entry.
- Includes many different types of health care stakeholders such as:
  - HINs
  - HIEs
  - Individuals
  - Providers
  - Federal agencies
  - Public health agencies
  - Health plans and other payers
  - Health IT developers
- Roles
  - QHIN
  - Participant
  - Participant Member
  - Individual User

# THREE MODALITIES OF EXCHANGE IN TEFCA

**QHIN Targeted Query:** a QHIN's electronic request for EHI ("pull") from specific QHINs in the context of the Common Agreement.

- Public health implications:
  - Immunization forecasting generated by an immunization information system.

**QHIN Broadcast Query:** a QHIN's electronic request for EHI in the context of the Common Agreement that requests EHI from all other QHINs.

**QHIN Message Delivery:** the electronic action of a QHIN to deliver EHI to one or more QHINs, or to send EHI to one or more QHINs for delivery to one or more Participants or Individuals ("push").

- Public health implications:
  - Syndromic surveillance.
  - Immunization reporting.
  - Cancer reporting.



# THE CA AND THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

- The HIPAA Privacy Rule and HIPAA Security Rule serve as the foundation for federal protection of the privacy and security of most individually identifiable health information. The Rules apply only to entities defined in the rules as Covered Entities and Business Associates.
- Many non-HIPAA entities offer useful and efficient services.
- Individuals, health care providers, health plans, and networks may not be willing to exchange data through the Common Agreement if non-HIPAA entities present privacy or security risks.
- To meet the goals of the 21<sup>st</sup> Century Cures Act as and to help address these concerns and encourage robust data exchange, the CA requires non-HIPAA entities to comply with provisions that align with the Rules.
- Public health implications:
  - Non-covered or hybrid entity.

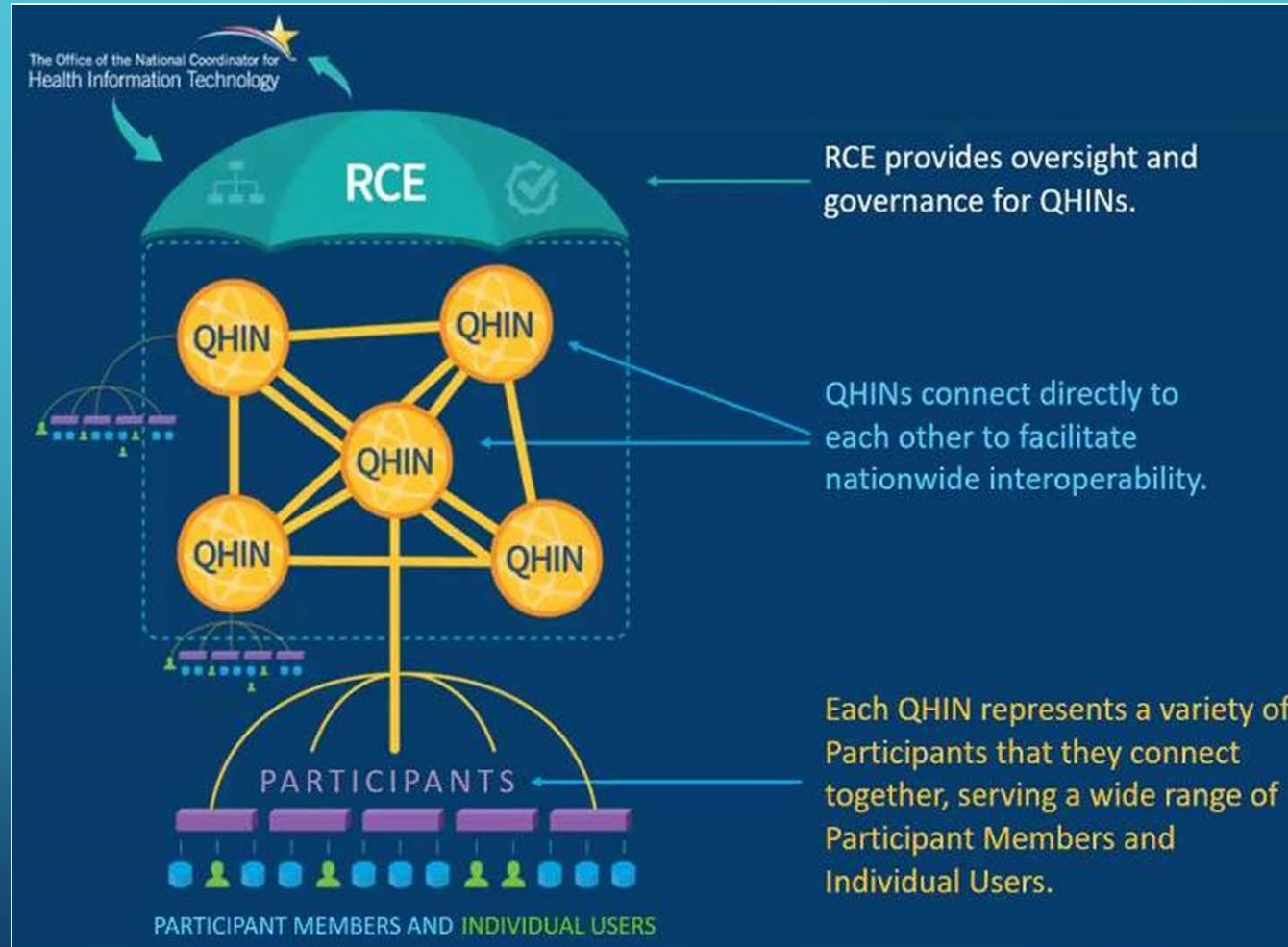
# RULES OF THE ROAD- MINIMUM TERMS AND CONDITIONS (MTRC)

- Covers all actors in trusted exchange (Qualified Health Information Networks (QHINs), participants connected to QHINs, or members and individual users connected directly to QHINs or to participants)
- Describes a proposed process for designating QHINs including anew designation of “provisional QHINs”
- Describes
  - Basic operations
  - Data quality
  - Transparency
  - Cooperation and non-discrimination
  - Privacy, security and patient safety
  - Minimum obligations for participants and members

# MEANINGFUL CHOICE AND WRITTEN PRIVACY SUMMARY

- Individuals need to understand and make informed choices about where, how, and with whom their EHI may be shared.
- QHINs, Participants, and Participant Members are required to provide Individuals with the opportunity to exercise *Meaningful Choice* to request that their EHI not be used or disclosed via the Common Agreement, except as required by applicable law.
- All QHINs, Participants, and Participant Members who provide Individual Access Services must publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, use, and disclosure of EHI.
- Public health implications:
  - Clarity about required and optional reporting.
  - Form collection.

# HOW WILL THIS WORK?



# EHI USE OUTSIDE THE UNITED STATES

- MRTCs Draft 2 does not permit QHINs to Use or Disclose EHI outside the United States, except to the extent that an Individual User requests his or her EHI to be used or disclosed.
- Public health implications:
  - Data storage.
  - 45 CFR 164.512 allows disclosure “[T]o an official of a foreign government agency that is acting in collaboration with a public health authority.”

# SECURITY LABELING

- Any EHI containing codes from one of the SAMHSA Consent2Share sensitivity value sets for mental health, HIV, or substance use in Value Set Authority Center (VSAC) must be electronically labeled.
- Any EHI of patients considered to be minors shall be electronically labeled.
- The data holder responding to a request for EHI must apply electronic security labels to the EHI.
- EHI shall be electronically labeled using the confidentiality code set as referenced in the HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata.
- Labeling shall occur at the highest (document or security header) level.

## Public health implications:

- Ability to modify systems.
- Granularity.
- Individuals requiring legally authorized representatives.

# CHANGES FROM TEFCA, VERSION 1

- Narrowing of the exchange “purposes” covered by TEFCA to align better with HIPAA
- Smaller agenda for initial implementation
  - Delay population-level data exchange
- Change in implementation timeline
  - Placing decision-making with the Recognized Coordinating Entity (RCE)
- Broadening of the definition of a QHIN
- Addition of “Push” messages
- Moving technical standards from within the TEF itself into a separate QTF
- Slight changes to rules around QHINs and charging fees
- Removal of explicit language stating that QHINs cannot charge to respond to queries for public health

# PUBLIC HEALTH OBSERVATIONS

- Public health continues to play a conspicuous role
- Explicit presence in the list of stakeholders
- Inclusion in the exchange purposes
- Recognition of the role of existing state and local consent laws as they affect information exchange
- Document and supporting material is well written
- Separation of the technical framework from the TEF into the QTF is also a big improvement
- General rubric of how the Common Agreement will work – it's essential hub and spoke design – is cleanly laid out and relatively straightforward



# “PUSH” TRANSACTION



What can the Common Agreement be used for?

The Office of the National Coordinator for Health Information Technology

## Exchange Purpose Example



- 1 Primary Care Provider (PCP) (Participant Member) provides an immunization to a patient and sends immunization record to QHIN A for Public Health
- 2 QHIN A initiates QHIN Message Delivery to send the immunization record to the appropriate QHIN B
- 3 QHIN B sends immunization record to the appropriate Participant
- 4 Participant delivers immunization record to the appropriate State Immunization Information System (Participant Member)

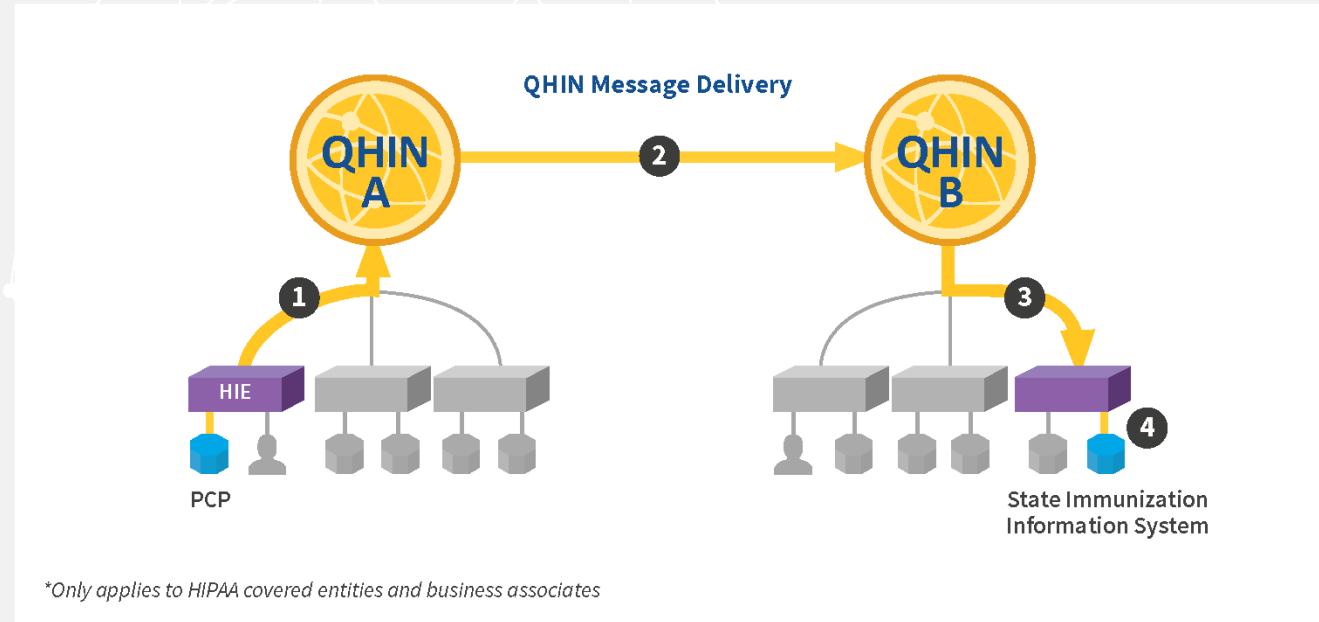


Diagram c/o ONC

# ISSUE TO BE ADDRESSED

- Initial implementation in QTF based on IHE standards
- Nominal recognition of HL7 FHIR as alternative
- Even if public health not required to use IHE intermediation by QHINs would “complicate” most current transactions
  - Note: National implementation of electronic case reporting (eCR) *does* support IHE XDR
- EHI not clearly defined
- Proposes to extend HIPAA privacy and security regulations to *all* TEFCA participants. Even public health?
- Issue of patient matching across the healthcare ecosystem continues to be a serious obstacle
- “Meaningful choice” is all or nothing – will choice not to participate mean public health reporting be the “baby thrown out with the bath water”?

## REFERENCE

### **Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2**

<https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>.

Blog: <https://www.hln.com/onc-gets-it-mostly-right-with-tefca-2-0/>

# DISCUSSION AND QUESTIONS

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# QUESTIONS AND CONTACT INFORMATION

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