Interoperability Matters Leadership Council

7/30/2019

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Leadership Council Members

Organization	Council Member*	Alternate*
The Badger Group	**Michael Matthews – Co-chair**	
American Medical Association	**Michael Hodgkins – Co-chair**	**Matt Reid**
athenahealth	Jared Esposito	Greg Carey
Azuba	Bart Carlson	
Cerner	Hans Buitendijk	
Community Care HIE (MedWare)	Victor Vaysman	
CRISP	David Horrocks	Ryan Bramble
CommonSpirit	Sean Turner	Ryan Stewart
eClinicalWorks	Navi Gadhiok	Tushar Malhotra
Ellkay LLC	Ajay Kapare	
Epic	Rob Klootwyk	Matt Becker
First Genesis	Joe Chirco	Tom Deloney
Glenwood Systems	Samuel Raj	
Greenway Health	Danny Shipman	
Health Gorilla	Steve Yaskin	
HealthCatalyst (formerly Medicity)	Ryan Barry	Jay Starr
HealthLX	Will Tesch	
HIMSS	Mari Greenberger	Amit Trivedi

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Leadership Council Members, cont.

Organization	Council Member	Alternate
Inovalon	Eric Sullivan	
Intermountain Healthcare	Stan Huff	Sid Thornton
Jackson Community Medical Record	Julie Lowry	
Kaiser Permanente	Jamie Ferguson	Keven Isbell
Kno2	Alan Swenson	Therasa Bell
lifeIMAGE	Matthew Michela	Richie Pfeiffer
MatrixCare	Doc DeVore	
Medent (Community Computer Services)	Kara Musso	
MedVirigina / Clareto	Steven Leighty	Stephen Hrinda
MiHIN	Drew Murray	Shreya Patel
MRO	David Borden	Rita Bowen
NeHII	Stefanie Fink	
NetSmart	AJ Peterson	
NextGen	Dan Werlin	Muhammed Chebli
NYeC	Valerie Grey	Alison Birzon
OCHIN	Jennifer Stoll	Paul Matthews
OneRecord	Jennifer Blumenthal	
Optum	Brian Lumadue	

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Leadership Council Members, cont.

Organization	Council Member*	Alternate*
Orion Health	Kave Henney	
PCC Pediatric EHR	Jennifer Marsala	
Safe Group	Ken Mayer	
SafetyNet Connect	Keith Matsutsuyu	
San Diego Health Connect	Nicholas Hess	Daniel Chavez
Santa Cruz HIE	Bill Beighe	
Social Security Administration	Stephen Bounds	Jude Soundararajan
Surescripts	Tara Dragert	Kathy Lewis
TASCET	Kari Douglas	
Updox	Michael Witting	
Virence Health (non-GE)	Kedar Ganta	
Walgreens	Renee Smith	Bindu Joseph
WOMBA	Eli Rowe	Moti Mitteldorf
Zen Healthcare IT	Marliee Benson	John Henry Downing
Zoll	Greg Mears	

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The Sequoia Project Team

Lindsay Austin, Troutman Sanders Strategies

Steve Gravely, Gravely Group

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Mark Segal, Digital Health Policy Advisors

Dawn Van Dyke, Director, Marketing Communications

Mariann Yeager, CEO

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Agenda

- Review Agenda
- Information Blocking Workgroup – Phase II [Advise]
- TEFCA Update and Role of Interoperability Matters [Inform]
- RCE Status Update [Inform]
- Member Engagement and Upcoming Events [Inform]

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Information Blocking Workgroup
Phase 2

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Information Blocking Workgroup: Purpose

- ✓ Provide input into Sequoia comments to ONC on proposed rule
- Identify practical, implementation-level implications of proposed and final information blocking rules, which may or may not be consensus positions
- Facilitate ongoing discussions to clarify information blocking policies and considerations prior to and after the Final Rule

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Workgroup Representatives

Associations and Orgs - health IT community
- Mari Greenberger, HIMSS
- Matt Reid, AMA
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust

Consumers
- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciitizen

Consultant
- Brian Ahier, MITRE Corporation

Federal Government
- Steve Bounds, SSA
- Margaret Donahue, VA

Health Information Networks and Service Providers
- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange
- Paul Uhrig, Surescripts, Co-Chair

Healthcare Provider
- David Camitta, CommonSpirit, Co-Chair
- Eric Liederman, Kaiser Permanente

Legal, Technology, Standards, and Policy Subject Matter Experts
- Jodi Daniel, Crowell & Moring, LLP
- Josh Mandel, Microsoft
- Micky Tripathi, MaEHC

Payers
- Nancy Beavin, Humana
- Danielle Lloyd, AHIP
- Matthew Schuller, BCBSA

Public Health
- John Loonsk, APHL

Vendors
- Aashima Gupta, Google
- Cherie Holmes-Henry, EHRA / NEXTGEN
- Rob Klootwyk, Epic
- Josh Mast, Cerner

Informatics
- Doug Fridsma, AMIA

Safety Net Providers / Service Provider
- Jennifer Stoll, OCHIN

Release of Information Company
- Rita Bowen, MROCorp

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Information Blocking Workgroup: Agenda for Future Meetings: Phase 2

Overall approach: Focus on implementation and compliance implications of ONC proposed rule elements and likely outcomes. Not relitigating comments.

- ✓ Meeting 1 (6/20) Review comments submitted and proposed workplan
- ❖ No July Call
- **Meeting 2 (8/2) HIE/HIN and Other Key Definitions**
- ❖ Joint Workgroup & Leadership Council (8/21) – In-person and virtual

  Registration: https://sequoiaproject.org/events/2019-in-person-meeting/
- Meeting 3 (9/13) Information Blocking Practices
- Meeting 4 (10/11) Recovering Costs/RAND Licensing
- Meeting 5 (11/8) Compliance Plans (or review Final Rule Out)
- Meeting 6 (12/13) Review Final Rule or TBD

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August Topic: HIEs/HINs and Related Key Definitions

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Definitions Providing Context for Discussion of HIE and HIN

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Information Blocking: ONC

§171.103 Information blocking.

Information blocking means a practice that—

(a) Except as required by law or covered by an exception set forth in subpart B of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(b) If conducted by a health information technology developer, health information exchange, or health information network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(c) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Electronic Health Information (EHI)

- Per §171.102, *electronic protected health information* (defined in HIPAA), and any other information that:
  - Identifies individual, or with respect to which there is a reasonable basis to believe the information can be used to identify individual; and
  - Transmitted by or maintained in electronic media (45 CFR 160.103) that;
  - Relates to past, present, or future health or condition of an individual; provision of health care to an individual; or past, present, or future payment for the provision of health care to an individual.
  - Not limited to information created or received by a provider
  - Not de-identified health information per 45 CFR 164.514(b)
- Could include price information but ONC has RFI on including price information within EHI with regard to information blocking

Interoperability Element §171.102

1. Any functional element of a health information technology, whether hardware or software, that could be used to access, exchange, or use electronic health information for any purpose, including information transmitted by or maintained in disparate media, information systems, health information exchanges, or health information networks.
2. Any technical information that describes functional elements of technology (such as a standard, specification, protocol, data model, or schema) and that a person of ordinary skill in the art may require to use functional elements of the technology, including for developing compatible technologies that incorporate or use functional elements.
3. Any technology or service that may be required to enable use of a compatible technology in production environments, including but not limited to any system resource, technical infrastructure, or health information exchange or health information network element.
4. Any license, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments.
5. Any other means by which EHI may be accessed, exchanged, or used.

Actors §171.102

Health Care Providers	Same meaning as "health care provider" at 42 U.S.C. 300jj—includes hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, emergency medical services provider, Federally qualified health center, group practice, pharmacist, pharmacy, laboratory, physician, practitioner, provider operated by, or under contract with, the IHS or by an Indian tribe, tribal organization, or urban Indian organization, rural health clinic, a covered entity ambulatory surgical center, therapist, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.
Health IT Developers of Certified Health IT	An individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health information technology (one or more) certified under the ONC Health IT Certification Program
Health Information Exchanges	Individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes
Health Information Networks	Health Information Network or HIN means an individual or 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 (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

HITAC on HIE and HIN

HIE

- *Health Information Exchange or HIE* means: ~~a Any individual or~~ entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the ~~that enables~~ access, exchange, transmittal, processing, handling or other such use of ~~e~~ Electronic ~~h~~ Health ~~i~~ Information. ~~primarily between or among a particular class of individuals or entities or for a limited set of purposes.~~

"We recognize that there are multiple uses of the terms "Health Information Network" (HIN) and "Health Information Exchange" (HIE) across the healthcare ecosystem. Having the terms overlap within the Proposed Rule is likely to cause a degree of confusion. We recommend making the following changes to the definitions of HIN and HIE:"

HIN

Health Information Network or HIN means an individual or entity that satisfies one or ~~both~~ several of the following— (1) Determines, oversees, administers, controls, or sets ~~substantially influences~~ policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange ~~enabling or facilitating access, exchange, or use of electronic health information~~ between or among two or more unaffiliated individuals or entities. (2) Provides, manages, or controls ~~or substantially influences~~ any technology or service that enables or facilitates Health Information Exchange ~~the access, exchange, or use of electronic health information~~ between or among two or more ~~unaffiliated~~ individuals or entities.

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Selected ONC Information Blocking Examples Relevant to Broadly Defined HIEs and HINs

- An HIN's participation agreement prohibits entities that receive EHI through the HIN from transmitting that EHI to entities who are not participants of the HIN.
- A health IT developer of certified health IT refuses to license an API's interoperability elements, to grant the rights necessary to commercially distribute applications that use the API's interoperability elements, or to provide the related services necessary to enable the use of such applications in production environments.
  - *What if an HIE or HIN has proprietary APIs or interoperability tools and methods??*
- An HIN charges additional fees, requires more stringent testing or certification requirements, or imposes additional terms for participants that are competitors, are potential competitors, or may use EHI obtained via the HIN in a way that facilitates competition with the HIN.
- An EHR developer of certified health IT charges customers a fee to provide interfaces, connections, data export, data conversion or migration, or other interoperability services, where the amount of the fee exceeds the actual costs that the developer reasonably incurred to provide the services to the particular customer(s).
  - *What if a broadly defined HIE or HIN charges fees for such or similar services that exceed costs?*
- A health IT developer of certified health IT adheres to the ''required'' portions of a widely adopted industry standard but chooses to implement proprietary approaches for ''optional'' parts of the standard when other interoperable means are readily available.
  - *Are "proprietary" implementations of APIs or other technologies by broadly defined HIEs and HINs information blocking? How is non-standard to be defined? Is a non-FHIR Restful API non-standard?*

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Actors and Other Definitions: Workgroup Findings

- The definition of an *actor* is critical because it exposes organizations to penalties and the regulatory implications of defined *practices* and *exceptions*.
- The proposed definition of an *HIN* is too broad and could include organizations that are not networks; it should be more narrowly focused:
  - For example, health plans, technology companies that handle *EHI*, and standards developing organizations (SDOs) or organizations that develop recommended interoperability polices are not networks and could, inappropriately, be included in the proposed definition.
  - Should receipt of health IT incentive program payments or federal stimulus payments be a determinant of whether an organization is an HIE or an HIN?
- The definition of an *HIE* includes *individuals*, which is difficult to understand, and, as with the *HIN* definition, could sweep in individuals or organizations that are not actually HIEs.
- The distinction between HIEs and HINs is unclear; HIEs should be viewed as a subset of HINs; ONC should therefore consider combining the two types of actors into one combined definition.
- The HIT *developer* definition needs more clarity on whether its application includes all *interoperability elements* under the control of the developer.
  - In addition, the definition is too broad as it could bring in companies that only have one product certified against one or a very few criteria, for example a quality reporting module.
  - The definition would also seem to inappropriately include organizations like value-added resellers in its focus on “offers” certified health IT.
- ONC should consider defining EHI to equal PHI as defined by HIPAA.

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Questions for the Workgroup

HIN Definitions

- *There is a broad consensus among commenters that the definitions of HIE/HIN is too vague and overlapping. Did the HITAC proposed revisions adequately address these concerns?*
- *What organizations could be included as HIEs or HINs that might not expect to be?*
- *Which kinds of potential HIEs and HINs should be planning for final rules that might not expect to be subject to these provisions?*
- *Which exceptions are likely to be most relevant to broad HIE and HIN definitions?*
- *Are there specific information blocking provisions or expectations that are likely to be especially challenging or unique in application to broadly defined HINs or HIEs (e.g., an SDO, a health plan, an interoperability services provider)?*

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Questions for the Workgroup

Interoperability Elements and HIEs/HINs

- *If ONC does not narrow this definition, how should we approach this from a compliance perspective?*
- *Will every HIE/HIN and other Actor needs to review and update all of its policies and procedures that relate to "access, use or exchange" of EHI?*
- *If so, this seems like a massive level of effort. How can we safely triage this work to concentrate on the most important first?*

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Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion

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TEFCA Update and Role of Interoperability Matters

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ONC’s Goals for the TEFCA

GOAL 1

Provide a single “on-ramp” to nationwide connectivity

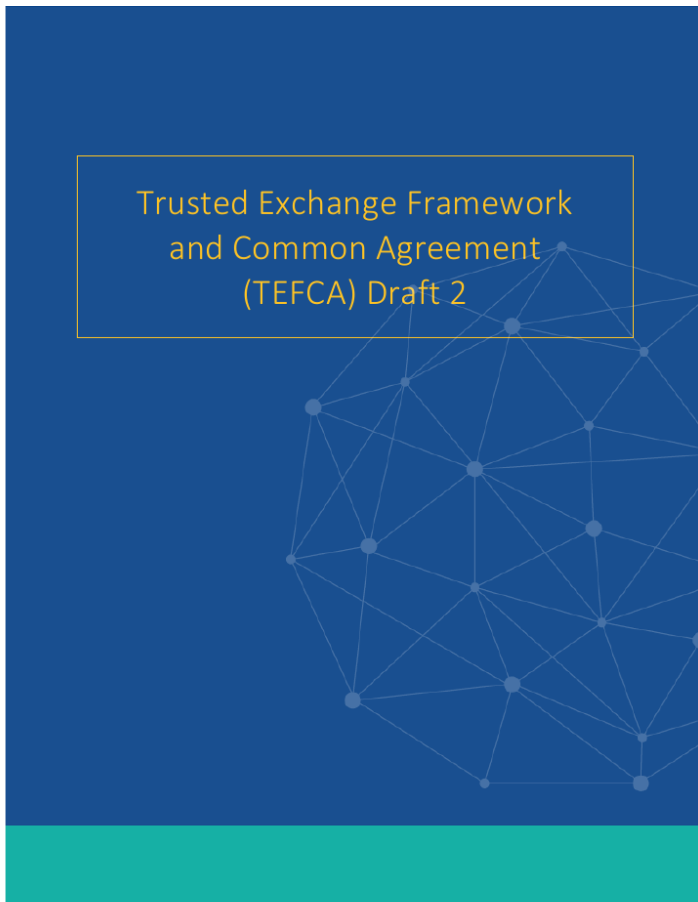
GOAL 2

Electronic Health Information (EHI) securely follows you when and where it is needed

GOAL 3

Support nationwide scalability

TEFCA Draft 2



- *Introduction to the Trusted Exchange Framework and Common Agreement (TEFCA)*
- *Appendix 1: The Trusted Exchange Framework (TEF)*
- *Appendix 2: Minimum Required Terms & Conditions (MRTCs)*
- *Appendix 3: Qualified Health Information Network (QHIN) Technical Framework*

Comments were due June 17; 100+ received
https://www.healthit.gov/tefcacomments?page=0

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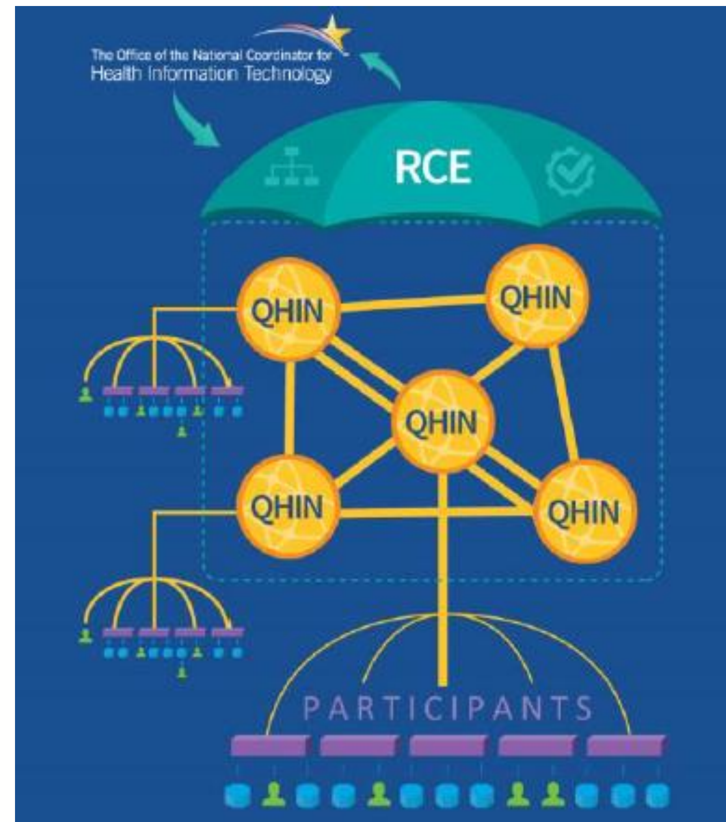
Overall Model

- RCE governs *QHINs* under Common Agreement, with operational oversight from ONC
  - To be selected by ONC per a Notice of Funding Opportunity for a Cooperative Agreement
- QHINs, in turn, have *Participants* (e.g., HIEs but could be broader)
  - Agreements flow-down
- Participants have *Participant Members* (e.g., provider organizations but could be broader)
- QHIN, Participant, or Participant Member can also serve a patient (or "Individual User") directly
  - Focus on individual right of access, "manually" invoked



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Common Comment Themes for ONC: Preliminary

- Meet congressional intent to support and not disrupt or duplicate existing exchange networks and frameworks and their trust agreements
- Reconcile TEFCA with HIPAA privacy and security regulations and information blocking and open API regulations
- Focus on how Individual Access Services will be implemented, including scope and role of apps and APIs
- Need for care in implementing Meaningful Choice, which would enable individuals to opt out of TEFCA exchange—can/should it be more granular and what should be limits on data shared before MC exercise
- The Recognized Coordinating Entity (RCE) should have significant leeway to work with stakeholders to refine/implement both policy and technical aspects of the TEFCA

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Highlights of The Sequoia Project's Comments

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Support:
Goals and Revisions within TEFv2

- Continued support for ONC's goals for TEFCA
- Appreciate changes made in TEFv2 in response to public feedback on TEFv1
- Strongly agree with TEFv2 change to **incorporate Qualified Health Information Network (QHIN) Technical Framework (QTF) by reference in the Common Agreement (CA)** and to be finalized by the RCE
- Support proposed role of and selection criteria of private-sector RCE
- Support role of the QHIN and agree with **changes to criteria to qualify as a QHIN to broaden participation opportunity**
- Agree **ONC/TEFCA will not dictate internal requirements** or structure of QHINs, Participants, or Participant Members
- Support TEFv2 revised exchange modalities and associated definitions
- Agree QHINs are **required to respond to all requests** for any approved exchange purpose as authorized by law, BAAs and other contracts

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Concern:
Disruption & Duplication of What's Working

- **TEFv2 risks not meeting congressional intent in Cures to avoid disruption and duplication** of "existing exchanges between participants of health information networks."
  - TEFv2 could both disrupt & duplicate existing exchange mechanisms
  - TEFv2 could require extensive changes to existing activities
  - TEFv2 could require revisions to thousands of legal agreements, which have taken years to develop and execute in support of large scale information sharing
  - TEFv2 could duplicate the Carequality Interoperability Framework "single on-ramp" developed by exchange community

ONC should seek every opportunity to minimize such disruption and duplication

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Concern:
Development of Required Terms and Conditions

- Additional Required Terms and Conditions (ARTCs) must be consistent with and not revise the Minimum Required Terms and Conditions (MRTCs), which were developed solely by ONC
- TEFv2 states RCE will develop the ARTCs in the future, with ONC approval, but must take MRTCs as final

ONC should collaborate closely with RCE to finalize MRTCs

RCE should engage QHINs, participants, and participant members in finalizing both the MRTCs and ARTCs

- The RCE will combine MRTCs and ARTCs into a data sharing agreement known as the Common Agreement

The Common Agreement should provide for phasing in of modalities / requirements to allow for faster and less disruptive roll-out

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Concern:
Narrow Set of Exchange Purposes

- TEFv2 narrows the set of exchange purposes based on public feedback received for TEFv1
  - Revised Payment and Operations set may exclude important use cases such as case management
  - Rigid requirements for immediate support of all specified exchange purposes

ONC should provide more precise definitions for the revised exchange purposes, being clear that they include case management and care coordination

Overall a full scope of Payment and Health Care Operations, as defined by HIPAA, should be included in TEFCA, with flexibility regarding support requirements

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Concern:
Exchange Outside of TEFCA

- QHINs, participants, and participant members are **not limited** to voluntarily offering additional exchange modalities and services or prevented from entering point-to-point/one-off agreements different from the MRTCs **so long as they do not conflict** with the Common Agreement
  - Sequoia supports this intent but is concerned additional clarity is needed

ONC/TEFCA should make clear agreements that do not involve operations under TEFCA are permitted to contain different policies than those in the CA, so long as activities under CA are fully compliant

ONC should be explicit that QHINs are not prohibited from participating in alternate (e.g. non-TEFCA) trust agreements

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Additional Suggestions:

- TEFCA needs to address material gaps in current exchange networks, such as **harmonization of agreed upon purposes of exchange and use of info**
- TEFCA needs further clarification that the focus is the collective capabilities of a QHIN and its constituents to provide the level of standards-based connectivity **regardless of connectivity model (federated, centralized, or mixed)**
- TEFCA/RCE will be strengthened **by additional and ongoing engagement mechanisms for QHINs, their participants, and participant members**
- ONC/TEFCA should continue and reinforce support for targeted queries
- **In addition to USCDI provisions, TEFCA participants should have flexibility to provide EHI necessary** for applicable use case

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Additional Suggestions:

- ONC should detail expectation of proposed TEF high-level principles and lack of compliance implications
- ONC should extend timeline of QHIN QTF development to allow more stakeholder feedback
- ONC/TEFCA should address participant fees more explicitly and comprehensively (e.g. limits, transparency, and disclosure)
- ONC/TEFCA should clarify when non-HIPAA covered entities or business associates must meet all HIPAA privacy and security provisions vs. MRTCs requirements
- ONC should allow more granular Meaningful Choice exercises than proposed
- ONC should assess the viability and burden of the Controlled Unclassified Information (CUI)
- Adoption of security labels is premature and would slow initial adoption of TEFCA. ONC/RCE should address in future ARTCs

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RCE Update

- The Sequoia Project submitted an application to be the RCE with essential contributors, Carequality and RTI, leveraging respective strengths
  - Sequoia: public-private convener, coordinated governance with ONC
  - Carequality: proven experience and expertise with existing operational model comparable to TEFCA
  - RTI: develop outcome / process measures for QHIN reports and support public listening session
- ONC is to announce the selected RCE by the end of August
- Listening sessions and stakeholder engagement are critical elements of the RCE function
  - Whether or not Sequoia is selected as the RCE, we expect to use Interoperability Matters and its Public Forum to provide input

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Member Engagement and Upcoming Events

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Three Types of Engagement (following restructure in 2018)

eHealth Exchange Participants

- Sign the DURSA, pay annual network fees and exchange data with other participants
- 230+ network participants
- Sequoia corporate membership not required, but is separately available with additional dues

Carequality Implementers

- Sign the CCA and pay annual implementer fees
- 26 implementers
- Prior to 9/12/18, implementers were also Sequoia members
- As of 9/12/18, new implementers may opt to also be Sequoia members with additional dues

The Sequoia Project, Inc. Corporate Members

- All existing members were carried over as Members of Sequoia
- Sequoia corporate dues required for continued membership, effective 10/1/19

https://sequoiaproject.org/about-us/membership/

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Sequoia In Person Meeting & Reception (8/21)

- Register to attend Sequoia members only event in-person or virtually: https://sequoiaproject.org/events/2019-in-person-meeting/
- Invitees: Sequoia Board, Members, Interoperability Matters Leadership Council and Information Blocking Workgroup
- NOT a part of the official ONC event agenda

Wednesday, August 21st, 2019

5:15 – 6:00 p.m. - Joint Meeting of the Leadership Council and Workgroup *(ALL Sequoia Project members are encouraged to attend)*

6 p.m. to 7 p.m. – Member Networking Reception

The Renaissance Hotel Meeting Room #3 (same hotel as the ONC meeting)

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Interoperability Matters Public Advisory Forum

- Next call: Friday, September 6th, 1:00 – 2:00 pm ET
- Agenda:
  - Updates from Leadership Council, Information Blocking Workgroup, and / or the RCE application
- The Public is invited to register to attend this virtual meeting: https://register.gotowebinar.com/register/3913904453828039180

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