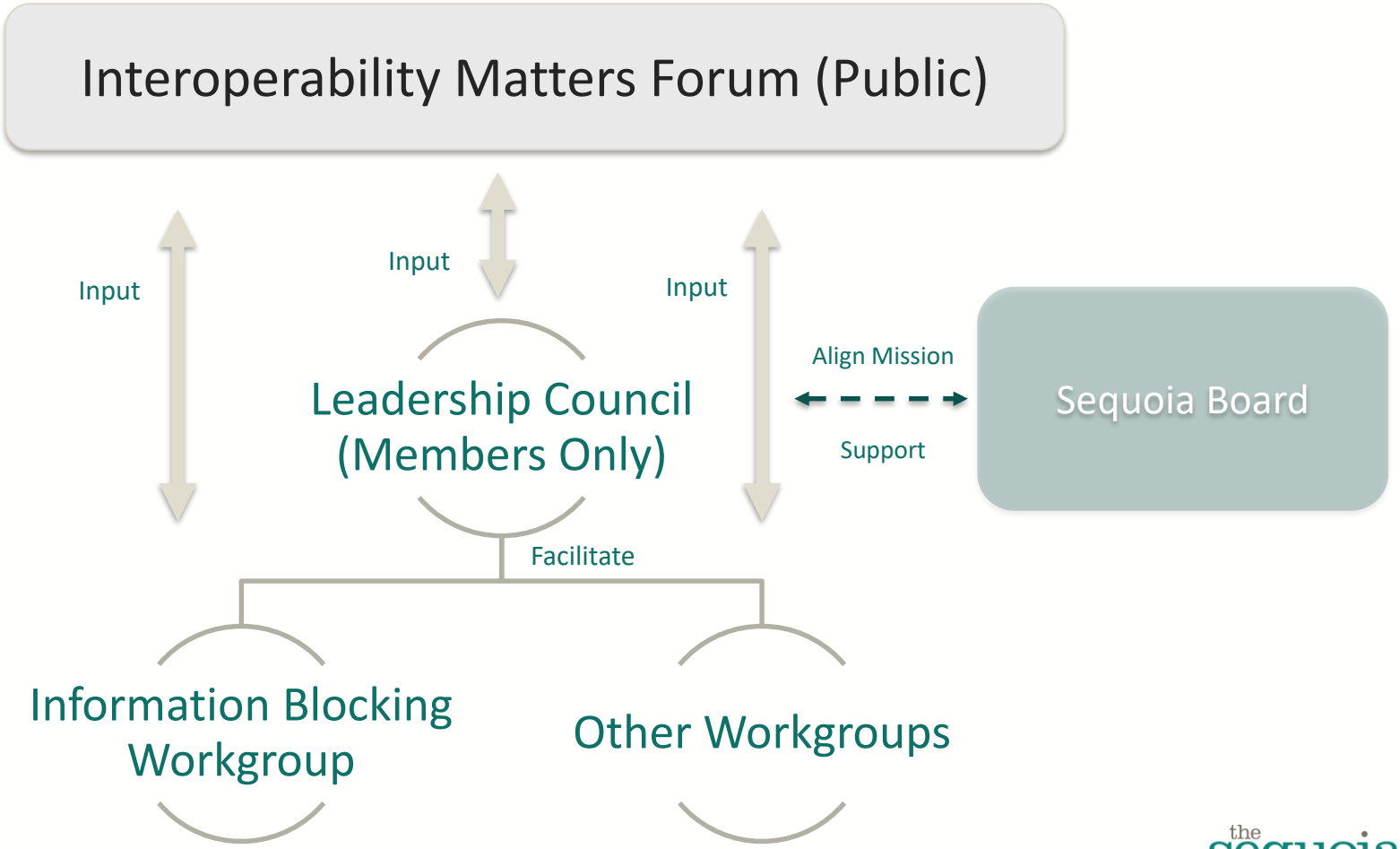
Interoperability Matters Public Advisory Forum

9/6/2019

Agenda

- Interoperability Matters Structure and Role of the Public Advisory Forum
- Status Update and Request for Public Input: Information Blocking Workgroup Phase II
- Sequoia Membership and Leadership Council Opportunities
- Next Steps

Interoperability Matters Structure



Interoperability Matters Forum (Public)

- Provides open, public forum to provide input and assure transparency
- Serves as listening session for staff, workgroup and Leadership Council
- Represents diverse private / public stakeholder and end user perspectives
- Provides input into the priorities and work products
- Enables community to share tools, resources and best practices
- Provides venue for policy makers to hear diverse perspectives in real-time

Options to participate in today's call

All lines are currently muted.

You may provide feedback in any of the following ways:

- If you would like to speak, please "raise hand" to be unmuted
- Use the "Chat" function to post a question or comment
- Send feedback following the call to interopmatters@sequoiaproject.org with the subject of "Public Advisory Forum"

The Sequoia Project Team

Lindsay Austin, Troutman Sanders Strategies

Steve Gravely, Gravely Group

Shawna Hembree, Program Manager

Mark Segal, Digital Health Policy Advisors

Dawn Van Dyke, Director, Marketing Communications

Mariann Yeager, CEO

Leadership Council Members

Organization	Council Member	Alternate
The Badger Group	**Michael Matthews – Co-chair**	
American Medical Association	**Michael Hodgkins – Co-chair**	**Matt Reid**
athenahealth	Kedar Ganta	Greg Carey
Azuba	Bart Carlson	
Bay Health Medical Center	Sue Saxton	Robin Yarnell
Blue Cross Blue Shield Association	Rich Cullen	Matthew Schuller
Cerner	Hans Buitendijk	
Community Care HIE (MedWare)	Victor Vaysman	
CRISP	David Horrocks	Ryan Bramble
CommonSpirit	Sean Turner	Ryan Stewart
eClinicalWorks	Navi Gadhiok	Tushar Malhotra
eHealth Exchange	Jay Nakashima	Katie Vizenor
Ellkay LLC	Gupreet (GP) Singh	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

Leadership Council Members, cont.

Organization	Council Member	Alternate
HealthLX	Will Tesch	
HIMSS	Mari Greenberger	Amit Trivedi
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	Karan Mansukhani
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

Leadership Council Members, cont.

Organization	Council Member	Alternate
OneRecord	Jennifer Blumenthal	OneRecord
Optum	Brian Lumadue	
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	
Walgreens	Renee Smith	Bindu Joseph
WOMBA	Moti Mitteldorf	Eli Rowe
Zen Healthcare IT	Marliee Benson	John Henry Downing
Zoll	Greg Mears	

Information Blocking Workgroup Status Update

Interoperability Matters

9/6/19

the sequoia project

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

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

Information Blocking Workgroup: Meeting Plan 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 (e.g. information blocking, electronic health information, interoperability elements)
- ✓ 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

Key Definitions: Workgroup Background

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 A~~~~n~~~~y 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.

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?*

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.

Implementation & Compliance Implications/Needs

HIEs/HIN Definitions: HITAC Proposed Revisions

- Definitions too confusing, even for expert likely more confusing in actual practice
- Proposed revisions positive, but still concerns, especially with broad EHI definition
- HITAC proposed revised HIE definition clearer, category overlap removed
  - Unusual to be an HIE if not an HIN.
- Revised HIN definition improved but still too broad, continued use of "or" between criteria underscores broad definition
- Guidance essential for final definitions., including likely scenarios
- Essential to understand how definitions used by enforcement agencies, such as OIG, ONC, and CMS and whether they have consistent interpretations
- Definitions will be used in other regulations and policies, like TEFCA
- Some broad scope may not matter (e.g., an EHR Developer that is a HIN would have no additional enforcement exposure)
- But, a health plan, not an "actor," could be an HIE or HIN and subject to regulations.
- Will take years for implications of definitions and other elements of enforcement to become clear, through cases and enforcement decisions
  - 25+ years for clarity around fraud and abuse/Stark/Anti-Kickback Statute/ Federal False Claims Act enforcement
- Risk of paralysis in organizational decision-making from policy ambiguity; clarity in definitions essential
- Common theme: definition breadth and overlap has real and practical implications.
- Workgroup can provide tools and perspectives to help organizations deal with ambiguity

Key Definitions: Workgroup Findings

Implementation & Compliance Implications/Needs

HIEs/HIN definitions: Who might be unexpectedly included?

- **Provider organizations**, especially those in ACOs where data sharing essential;
- **Payers** (HIEs/HINs, even under HITAC revision, especially with focus on "agreements");
- "**Individuals**" who "substantially influence" policies (e.g., HIM professionals, privacy officers);
- **Release-of-Information vendors**;
- **Interoperability and interface vendors** and any **organization with "integration" in name or mission**, for example:
  - **Third party integrators** working with health plans and providers
  - Companies providing **technology and technology support for HIEs and HIT developers**;
- **Clinical registries (**many need to use non-standard data elements and terms);
- **Companies that rely on remote data access** for their core functionality, such as analytics and clinical decision support vendor**s**;
- **Standards Development Organizations** (SDOs) and other **organizations that define policies and standards** for the industry; and
- **Digital wellness vendors**

Implementation & Compliance Implications/Needs

HIEs/HIN Definitions

Exceptions

- Unclear which likely most relevant to broad HIE/HIN definitions
- Exceptions proposed by ONC because they promote a public interest/ greater good, not to reduce actor burden and not as safe harbors
- Recent CMS interoperability proposed rule has detailed contractual requirements for health plans for interoperability but no exceptions, which plans may need

Provisions likely to be especially challenging or with unique in application to broadly defined HINs or HIEs

- Limits on non-standard technology
- Pricing requirements/exceptions
- Contracting rules (e.g., RAND terms
- Documentation requirements – many organizations that may be included as HIEs and HINs are less experienced with compliance-related documentation requirements
- "Individuals" defined as HIEs or HINs

Implementation & Compliance Implications/Needs

Interoperability Elements and HIEs/HINs: Organizational Priorities

- Actors and *potential actors* should think about all issues associated with information blocking compliance
- Plan for the worst case
- Challenging to ensure that smaller clinician practices obtain needed compliance expertise and resources
  - Some clinician practices may find themselves HIE or HINs
- Implementing certain exceptions will require organizational policies and procedures *and* need to integrate these into workflows
  - e.g., "minimum necessary" sub-exception requirements exceed what HIPAA requires
- Important for organizations to think about information blocking implications and obligations for parties with which they do business; threats and opportunities
- Physicians, other clinicians, and provider organizations will continue to view themselves as stewards of patient information and have concerns about vetting apps and API access, despite OIG guidance on HIPAA right of access
- Some organizations may face high volume of requests for information and will have challenges in handling volume
- Ambiguity in definitions and policies will make planning for compliance harder (e.g., actors, EHI vs. PHI, etc.)
- Audits may later show what you thought was best and sufficient effort not good enough, leading to unexpected liability

Membership Opportunities & Upcoming Events

Members are Critical to Guiding Sequoia's Future

- Founded Sequoia as non profit operating for the public good
- Majority representation on Sequoia board
- Instrumental in guiding the company's direction
- Approved corporate restructure to three companies
- Approved transition of all corporate members to the new Sequoia Project
- Lead Interoperability Matters
- For a list of members: https://sequoiaproject.org/about-us/members/

Sequoia Member Led Initiatives

- Interoperability Matters
  - Information Blocking Work Group
  - New project under consideration – Improving Semantic Interoperability
- Improving Interoperability of C-CDA and Content Testing
- Improving Patient Matching – Uniform Rules and Maturity Model

Interoperability Matters Leadership Council

- Sequoia Member led
  - Chartered Information Blocking Work Group
  - Approved the findings and recommendations that were provided along with the CMS and ONC Comment Letters
  - Provides strategic direction
  - Assures process is open, transparent and inclusive
  - Explores and prioritizes new projects
  - Will provide input regarding RCE and TEFCA

Join Us

Full Members (Key Contributors)

- 2 registrations for annual meeting **($2K value)**
- Access to The Sequoia Project Interoperability Testing Platform
  - Free access to C-CDA content tool and validation of 1st 10 data source **($3K value)**
  - 20% discount off transport testing tool annual subscription **($4K value)**
- Quarterly Webinars
- Interoperability Matters Leadership Council Representation
- Priority for leadership in workgroups and pilots
- Access to Members-only website (Coming Soon)

Associate Members (Contributors)

- 1 registration for annual meeting **($1K value)**
- Quarterly Webinars
- Interoperability Matters Leadership Council Representation
- Eligible to participate in workgroups

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

Contact us: admin@sequoiaproject.org

Sequoia Board of Directors

- Size is 11 to 21 voting members, plus CEO (ex officio) and government liaisons
- Members elect minimum of 7 and max of 15 Directors
- Board can appoint up to 6 at-large Directors
- Broad stakeholder engagement required in bylaws
  - 1-4 provider orgs, physicians, others
  - 1-3 health information networks (HIN)
  - 1-3 healthcare tech vendors or service providers
  - 1-2 health plans
  - 1-2 individuals or organizations representing consumer interests
  - 1-2 standards development organizations (SDO) or standards accelerator initiative

Next Steps

- Workgroup Meeting 9/13: Information Blocking Practices
- Next Public Advisory Forum Call: TBA Late October / Early November
- We invite you to submit additional feedback on today's workgroup topic via InteropMatters@sequoiaproject.org

Interoperability Matters

https://sequoiaproject.org/interoperability-matters/