



# Interoperability Matters Public Advisory Forum

*3/14/2019*

# Agenda

- Introduction
- Interoperability Matters Overview
- Leadership Council
- Public Advisory Forum
- Information Blocking Workgroup
- Timeline

# The Sequoia Project Team

**Lindsay Austin**, Troutman Sanders Strategies

**Didi Davis**, VP, Informatics, Conformance & Interoperability

**Steve Gravely**, Gravely Group

**Shawna Hembree**, Program Manager

**Mark Segal**, Digital Health Policy Advisors

**Dawn VanDyke**, Director, Marketing Communications

**Mariann Yeager**, CEO

# Interoperability Matters Cooperative Function

- Prioritize matters that benefit from national-level, public-private collaboration
- Focus on solving targeted, high impact interoperability issues
- Engage the broadest group of stakeholders and collaborators
- Coordinate efforts into cohesive set of strategic interoperability directions
- Channel end user needs and priorities
- Bring forward diverse opinions, which may or may not result in consensus
- Facilitate input and develop work products, with implementation focus
- Support public forum for maximum transparency
- Provide feedback based upon real world implementation to policy makers
- Deliver work products and implementation resources

# Interoperability Matters Process



## Sequoia Board

- Approves priorities, charters, resources
- Assures alignment with Sequoia mission
- Board Committee supports Cooperative, in consultation with Leadership Council
- Approves official Sequoia policy positions



## Leadership Council

- Facilitates Cooperative
- Recommends priorities to Board
- Charters Workgroups, with Board approval
- Oversees Workgroup process
- Assures advisory Forum input
- Presents findings, recommendations, work products to Board



## Work Group

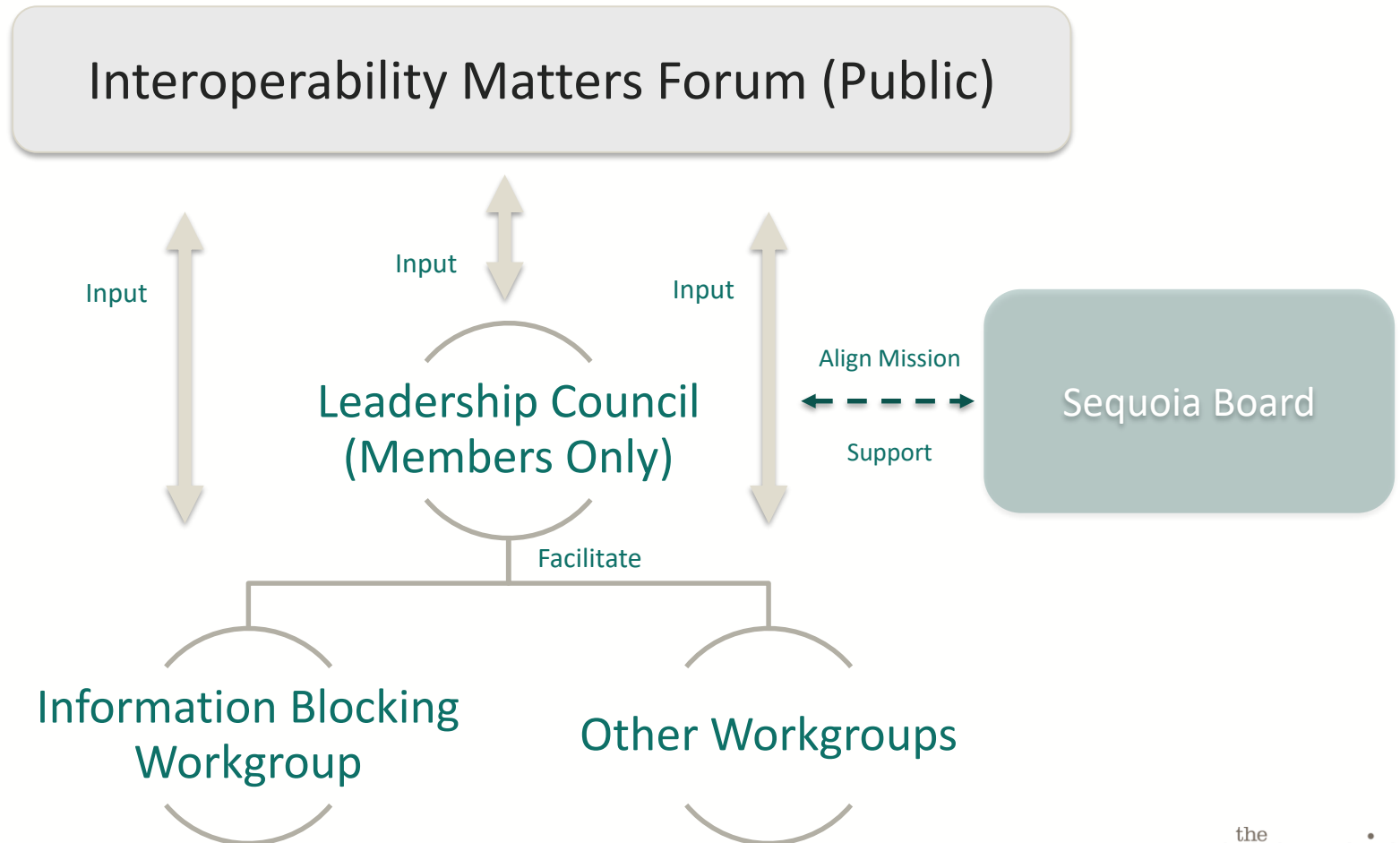
- Conducts detailed work
- Drafts findings, recommendations, work products
- Enlists input from advisory Forum
- Presents its work to Leadership Council for acceptance



## Interoperability Matters Forum

- Convened public forum
- Provides input to Leadership Council and Workgroups
- Reflects diverse perspectives
- Is informed of progress
- Support Affinity Groups if consensus or input sought from particular perspective

# Interoperability Matters Structure



# Sequoia Board Committee Role

- Facilitates coordination role on pilot basis
  - Board may appoint non-Board members to the Committee
  - Enables opportunity to learn and adapt
- Responsibilities
  - Aligns with Sequoia mission, without directing priorities / work
  - Serves as steward of resources (e.g. approval to support priorities)
  - Oversees inclusive volunteer and leadership recruitment
  - Assures appropriate collaboration and stakeholder engagement
  - Assures the process enlists and communicates diverse perspectives
  - Coordinates with Leadership Council
  - Presents informal recommendations to Board
  - Recommends board approval of official findings and recommendations to policymakers

# Interoperability Matters Sequoia Board: Interoperability Planning Committee

**Brian Ahier**, Medicity

**Nancy Beavin**, Humana

**Peter DeVault**, Epic

**Matt Eisenberg**, MD, Stanford University Health System

**Jamie Ferguson**, Kaiser Permanente

**Steven Lane**, MD, Sutter Health

**Paul Uhrig**, Surescripts



# Interoperability Matters Leadership Council

- Council Co-chairs:
  - **Michael Matthews**, The Badger Group, Co-Chair
  - **Michael Hodgkins**, American Medical Association, Co-Chair
- Structure: Members-Only (Voting and Non-Voting)
- Role
  - Facilitates the Cooperative's work
  - Consults with Sequoia Board Committee and Interoperability Matters Forum on priorities
  - Develops workgroup charters, subject to board approval
  - Coordinates workgroup and advisory Forum efforts
    - Recruits workgroup members
    - Tracks workgroup progress and guides effort
    - Assures appropriate input from advisory Forum
  - Provides substantive input to Board Committee and workgroups
    - Shares guidance, observations and other perspectives
    - Vets work group deliverables prior to submission to Board Committee
    - Considers advisory Forum input
  - Serves as liaison to Sequoia Board Committee
    - Presents recommended priorities
    - Reports status and progress
    - Presents deliverables and recommendations

# Interoperability Matters Public Advisory Forum

- 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

# Prioritization Process

- Proposals for a project may come from any source
- Proposals are submitted to the Leadership Council for consideration
- Leadership Council vets and narrows down proposed projects
- Leadership Council facilitates input from Interoperability Matters Forum
- Leadership Council finalizes priorities in consultation with Sequoia Board
- Sequoia Board assures alignment with Sequoia mission
- Sequoia Board approves resources to support the proposed projects

# Work Product / Adoption Process

Example: Coordinated Implementation Plan (e.g. C-CDA,USCDI Evolution)

- Leadership Council charters workgroup in consultation with Board Committee
- Leadership Council recruits workgroup members
- Workgroup facilitates work (e.g. deployment timeline, versioning, etc.), with Sequoia facilitator and staff support
- Workgroup co-chairs brief Leadership Council regarding its work
- Leadership Council co-chairs brief Board Committee regarding workgroup
- Workgroup shares progress and enlists input from Interoperability Matters Forum
- Interoperability Matters Forum shares perspectives in public meeting
- Workgroup considers input and recommends rollout plan
- Sequoia Board approves official Sequoia positions, findings and/or recommendations to policymakers

# Public Policy/Comment Process

## Information Blocking Workgroup

- Leadership Council charters workgroup in consultation with Sequoia board
- Sequoia staff / facilitators prepare materials for facilitated Workgroup discussions
- Workgroup Co-Chairs facilitate workgroup calls with staff and facilitator support
- Interoperability Matters Forum consulted regarding specific matters
  - Iterative basis as timeline permits
  - Focus on key questions, assumptions, interpretations, policy positions
  - Gauge where consensus and enlists diverse perspectives
- Workgroup convenes to:
  - Draft findings and recommendations based upon input
  - Include additional opportunities for public comment in Workgroup calls
  - Consult with Leadership Council
  - Finalize findings and recommendations
  - Present to Leadership Council for approval
- Leadership Council shares approved findings / recommendations with Board Committee
- Board Committee advises Sequoia Board (e.g. share, endorse, approve)



# Information Blocking Workgroup

# Purpose

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

# Composition

- Public call issued to serve on forum, regardless of Sequoia affiliation
- Open to all stakeholders, with the following represented at minimum:
  - Associations and organizations representing health IT community
  - Federal government representatives
  - Health information networks and service providers
  - Healthcare provider organizations, physicians and other clinicians
  - Individuals
  - Payers
  - Public Health
  - Subject matter experts (legal, privacy, information sharing policy, technology, standards)
  - Vendors (e.g. EHR, health IT to connect to EHRs, 3<sup>rd</sup> party integrators, consumer apps)
- Emphasis on experience applying information sharing policies and rules within their respective organizations



# Leadership and Staffing

- Two co-chairs lead the Workgroup
  - Have subject matter expertise, leadership and facilitation skills
  - Represent different stakeholder groups
  - May engage other stakeholders and SMEs to support work
  - Establish subgroups as necessary, with reports to Workgroup
- Sequoia staff and facilitators support Workgroup
  - Conduct analysis
  - Prepare discussion materials
  - Facilitate discussion of specific matters
  - Prepare deliverables

# Information Blocking Workgroup: Members and Staff

- Workgroup Co-Chairs
  - David Camitta, MD, Dignity Health
  - Paul Uhrig, Surescripts
- Staff Support and Facilitators
  - Steve Gravely
  - Shawna Hembree
  - Mark Segal
  - Mariann Yeager

# Workgroup Representatives

## Associations and Orgs - health IT community

- Lauren Riplinger, AHIMA
- Matt Reid, AMA
- Tom Leary / Mari Greenberger, HIMSS\*

## Consumers

- Ryan Howells, CARIN Alliance

## Federal Government

- Steve Bounds, SSA\*
- Margaret Donahue, VA

## Health Information Networks and Service Providers

- Dave Cassel, Carequality
- Chuck Christian, IHIE
- Brian Ahier, Medicity / Health Catalyst
- Paul Uhrig, Surescripts, Co-Chair

## Healthcare Provider

- David Camitta, Dignity, Co-Chair
- Wendy Angelo, Indiana Regional Med. Center\*
- Eric Liederman, Kaiser Permanente

## Legal, Technology, Standards, and Policy Subject Matter Experts

- Micky Tripathi, MaEHC
- Deven McGraw, Ciitizen
- Jodi Daniel, Crowell & Moring, LLP\*
- Josh Mandel, Microsoft

## Payers

- Danielle Lloyd, AHIP\*
- Matthew Schuller, BCBSA\*
- Nancy Beavin, Humana

## Public Health

- John Loonsk, CGI

## Vendors

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

## Informatics

- Doug Fridsma, AMIA

## Safety net providers / service provider

- Jennifer Stoll, OCHIN

## Release of Information Company

- Rita Bowen, MROCorp

*\*Invited*

# Workgroup Member Responsibilities

- Maintain personal involvement in Workgroup meetings
- Respect any confidential discussions held in the Workgroup
- Represent necessary expertise to contribute to Workgroup deliverables
- Enlist feedback from the constituents represented
- Balance personal perspectives with those of the constituency represented
- Gain input from and communicate to constituency
- Accept occasional assignments tasks between Workgroup meetings

# Workgroup Process

- Open, inclusive, consensus-based process, with ability to move forward and capture range of views expressed
- Facilitate formal process (e.g. published meeting agenda, meeting notes with roll, outcomes, Workgroup roster, documented decisions, etc.)
- Accommodate and reflect varying community perspectives and needs
- Focus on priority use cases consistent with Sequoia's mission and Interoperability Matters
- Remain vendor, provider, and technology neutral

# Consensus and Decision-Making

- Aim for consensus, where possible
- With or without consensus
  - Assure diverse stakeholder views heard
  - Identify areas of agreement
  - Capture diverse perspectives
  - Consider recommendations for further study to move towards consensus
  - Document the range of positions

# Phased Work

- Phase I: Review and provide perspectives on information blocking provisions of ONC proposed rule
- Phase II: Self-identify additional work items
  - Guidance and development of consensus points on practices relevant to information blocking laws and regulations
  - Input to federal government on implementation of information blocking laws and regulations
  - Provide subject matter expertise to support development and maintenance of information blocking-related materials to support the community.
  - Use webinars, wikis, online surveys and other mechanisms to gain community feedback
  - Conclude at discretion of Leadership Council, in consultation with Sequoia Board

# Deliverables

- Perspectives on ONC 21<sup>st</sup> Century Cures proposed rule that inform industry and Sequoia Project regulatory comments
- Assessments of proposed rule implications to the community
- Assessments of ONC proposed rule, with identified follow-up actions needed by federal government and private sector

7424 Federal Register / Vol. 84, No. 42 / Monday, March 4, 2019 / Proposed Rules

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Office of the Secretary**  
45 CFR Parts 170 and 171  
RIN 0955-AA01

**21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program**

**AGENCY:** Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).  
**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

**DATES:** To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 3, 2019.

**ADDRESSES:** You may submit comments, identified by RIN 0955-AA01, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- **Federal eRulemaking Portal:** Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.
- **Regular, Express, or Overnight Mail:** Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.
- **Hand Delivery or Courier:** Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

**Enhancing the Public Comment Experience:** To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format on ONC's website (<http://www.healthit.gov>). We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document ("public comment template") will also be made available on ONC's website (<http://www.healthit.gov>) for the public to use in providing comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on proposals and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages. We believe that use of the document may facilitate our review and understanding of the comments received. The public comment template will be available shortly after the proposed rule publishes in the *Federal Register*. This short delay will permit the appropriate citation in the public comment template to pages of the published version of the proposed rule.

**Inspection of Public Comments:** All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number, date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

**FOR FURTHER INFORMATION CONTACT:** Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202-690-7151.

**SUPPLEMENTARY INFORMATION:**

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- Executive Summary
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  - Summary of Major Provisions and Clarifications
  - Regulatory Actions for Previous Rulemakings
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  - Adoption of the United States Core Data for Interoperability as a Standard
  - Electronic Prescribing
  - Clinical Quality Measures—Report
  - Electronic Health Information Export
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  - Data Segmentation for Privacy and Consent Management
- Modifications to the ONC Health IT Certification Program
  - Health IT for the Care Continuum
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  - Statutory Basis
  - Standards, Implementation Specifications, and Certification Criteria
  - Health IT Certification Program(s)
  - Regulatory History
  - Standards, Implementation Specifications, and Certification Criteria Rules
  - ONC Health IT Certification Program Rules
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  - Background
  - History of Burden Reduction and Regulatory Flexibility
  - Executive Orders 13771 and 13777



# Key Concepts for Workgroup Review

## Actors

- Health Care *Providers*
- *Developers* of Certified Health IT
- Health Information *Exchanges*
- Health Information *Networks*

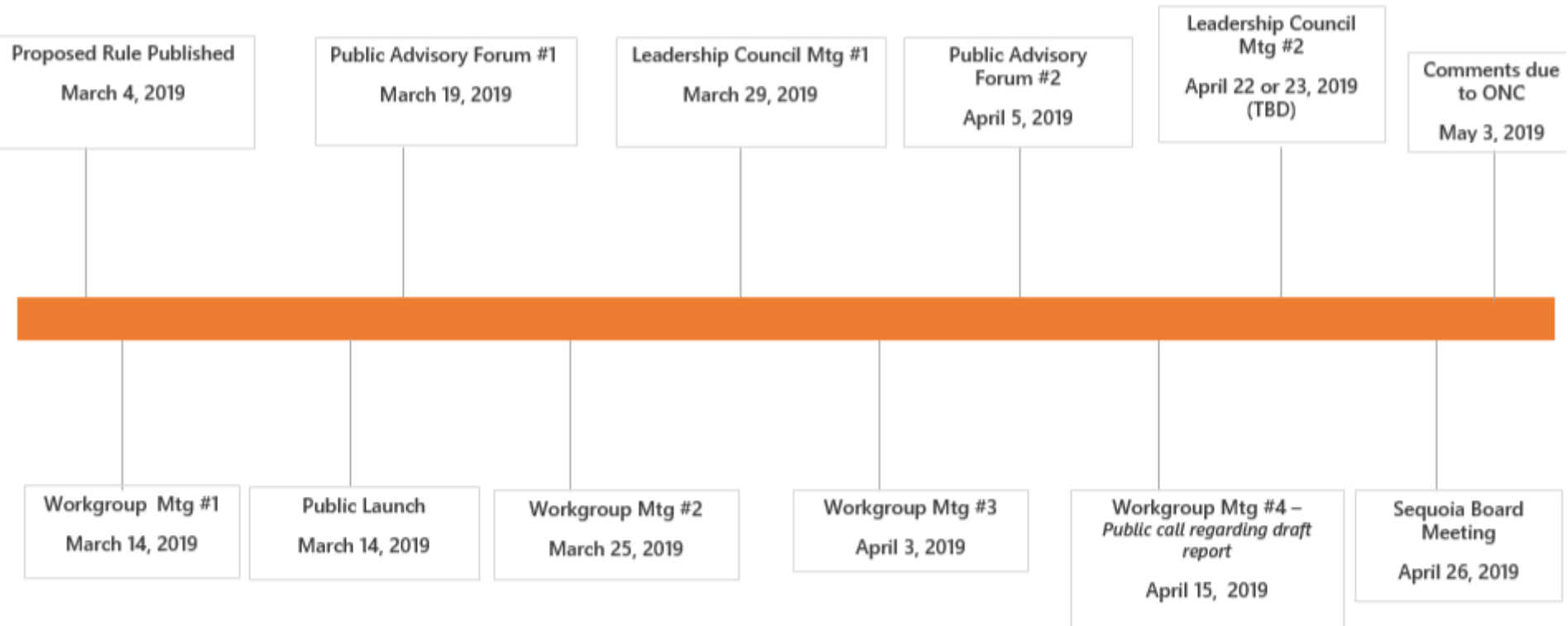
## Blocking Practices

- *Restrictions on access, exchange, or use* of EHI through formal means (e.g., contractual restrictions) or informal means (e.g., ignoring requests to share EHI)
- *Limiting or restricting the interoperability of health IT* (e.g., disabling a capability that allows users to share EHI with users of other systems)
- *Impeding innovations and advancements* in access, exchange, or use of health IT-enabled care delivery (e.g., refusing to license interoperability elements to others who require such elements to develop and provide interoperable services)
- *Rent-seeking and other opportunistic pricing practices* (e.g., charging fees to provide interoperability services that exceed actual costs incurred to provide the services)
- *Non-standard implementation practices* (e.g., choosing not to adopt relevant standards, implementation specifications, and certification criteria)

## Exceptions

1. Engaging in practices that prevent harm
2. Engaging in practices that protect the privacy of EHI
3. Implementing measures to promote the security of EHI
4. Recovering costs reasonably incurred
5. Declining to provide access, exchange, or use of EHI if a request is infeasible
6. Licensing technologies or other interoperability elements that are necessary to enable access to EHI
7. Making health IT unavailable to perform maintenance or improvements

# Key Milestones



Confirmed Times and Registration for Public calls  
will be posted at <https://sequoiaproject.org/events/>

# Interoperability Matters

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