Interoperability Matters Leadership Council

3/29/2019

the sequoia project

Agenda

- Review of Agenda
- Introduction of Leadership Council and Interoperability Matters
- Information Blocking Workgroup Status update
- Leadership Council Feedback on Initial Workgroup Discussions
- Milestones/Timeline
- Recommendations from Leadership Council for Cooperative Next Steps

Interoperability Matters Leadership Council

the sequoia project

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
Dignity Health	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 Travedi

**please confirm*

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	Theresa 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
NetSmart	AJ Peterson	
NYeC	Valerie Grey	Alison Birzon
OneRecord	Jennifer Blumenthal	
Optum	Brian Lumadue	
Orion Health	Kave Henney	
PCC Pediatric EHR	Jennifer Marsala	

**please confirm*

Leadership Council Members, cont.

Organization	Council Member*	Alternate*
QSI(NextGen/Mirth)	Dan Werlin	Muhammed Chebli
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)	Kadar Ganta	
Walgreens	Renee Smith	Bindu Joseph
WOMBA	Eli Rowe	Moti Mitteldorf
Zen Healthcare IT	Marliee Benson	John Henry Downing
Zoll	Greg Mears	

**please confirm*

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

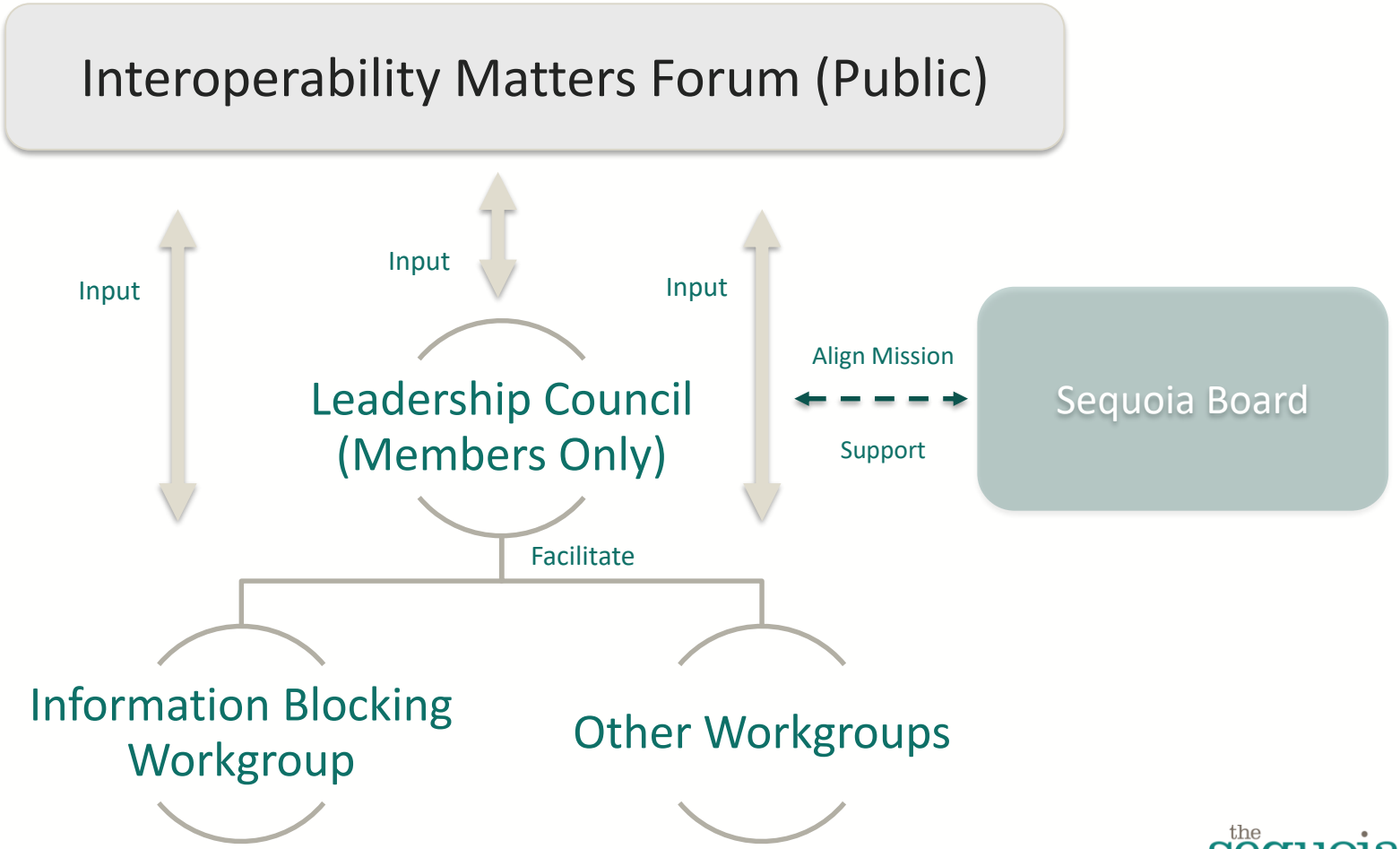
Work Group

- 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



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

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

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
- First meeting was March 19 and the second is April 5.

Information Blocking Workgroup Status Update

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

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)

Workgroup Representatives

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

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

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, Dignity, Co-Chair
- Eric Liederman, Kaiser Permanente

**Invited*

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, Johns Hopkins University

Vendors
- Brian Ahier, Medicity / Health Catalyst
- 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

Workgroup Process

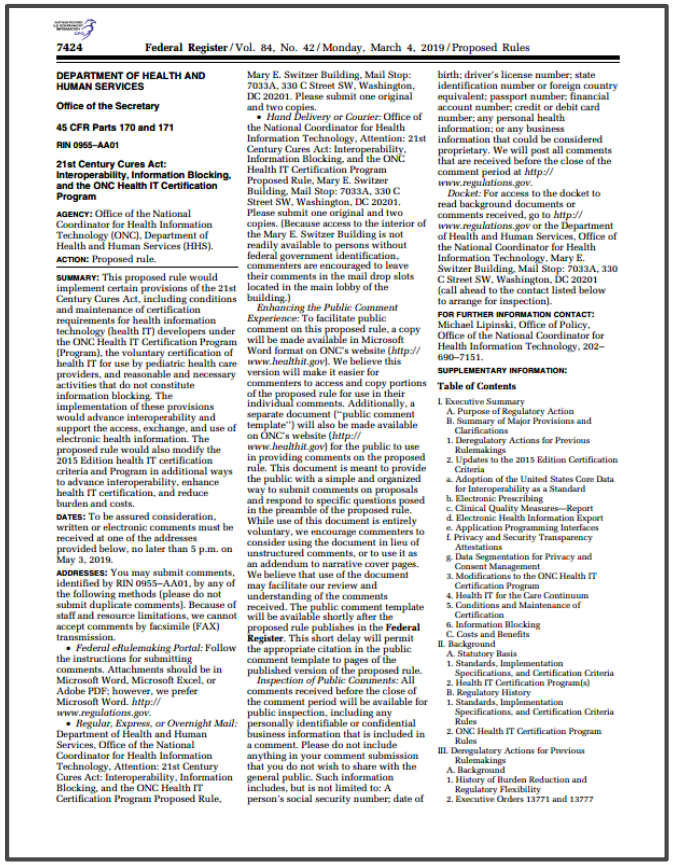
- Open, inclusive, consensus-based process, with ability to move forward and capture range of views expressed
- Facilitate formal process (e.g. published meeting agenda, meeting notes with roll, outcomes, Workgroup roster, documented decisions, etc.)
- Accommodate and reflect varying community perspectives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

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 21st 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*) 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:

Table of Contents

Information Blocking Workgroup: Scope and Focus of Review

- Primary: *Information Blocking* part of ONC proposed rule
  - Definitions (including Information Blocking Practices and Actors)
    - Identify implications and suggest revisions
  - Information blocking practices with examples
    - Add, revise, delete
  - Reasonable and Necessary Exceptions
    - Add, revise, delete
    - Activities that are info blocking, but are reasonable and necessary according to ONC criteria
  - Specific ONC comments sought
  - ONC RFI: disincentives for providers and price transparency
  - Complaint process and enforcement
- Secondary:
  - Information Blocking elements of Conditions and Maintenance of Certification, including enforcement

Note: Cures statutory provisions are out of scope for recommended changes other than for information and as a point of reference

Agenda: Workgroup Meeting #1: March 14, 2019

- Welcome and Introductions
- Workgroup Overview Refresh
- Actors and Other Definitions
  - Providers
  - CEHRT Developers
  - HIEs
  - HINs
- Information Blocking Practices
- Exceptions
  - Harm
  - Privacy
  - Security
- Next Steps

Actors Defined §171.102 – Focus of WG #2

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

HIEs and HINs

HIE

- Include but not limited to RHIOs, state HIEs, other organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties or for particular purposes
- Might facilitate or enable access, exchange, or use exclusively within a region, or for a limited scope of participants and purposes (e.g., registry or exchange established by hospital-physician organization to facilitate ADT alerting)
- May be established for specific health care or business purposes or use cases
- If facilitates access, exchange, or use for more than a narrowly defined set of purposes, may be HIE and a HIN

HIN

- Entity established in a state to improve movement of EHI between providers operating in state; identifies standards for security and offers Ts and Cs for providers wishing to participate in the network.
- Entity offering (and overseeing and administering) Ts and Cs for network participation
- Health system administers agreements to facilitate exchange of EHI for use by unaffiliated family practices and specialist clinicians to streamline referrals
- Individual or entity that does not directly enable, facilitate, or control movement of information, but exercises control or substantial influence over policies, technology, or services of a network
- A large provider may decide to lead effort to establish a network that facilitates movement of EHI between group of smaller providers (and the large provider) and through technology of health IT developers; large provider, with some participants, creates a new entity that administers network's policies and technology
- Note: Network is never defined

Are distinctions clear? Too broad or too narrow? Consistent with congressional intent?

Actors: Draft* Discussion Points

- 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 on 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.

*Not reviewed by the workgroup

Information Blocking Practices

Cures Statute

- (A) practices that restrict authorized *access*, *exchange*, or *use* under applicable State or Federal law of such information for *treatment and other permitted purposes* under such applicable law, including transitions between certified health information technologies;
- (B) implementing health information technology in *nonstandard* ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information;
- (C) implementing health information technology in ways that are likely to— ‘‘(i) restrict the access, exchange, or use of electronic health information with respect to *exporting complete information sets* or in *transitioning between health information technology systems*;
- or ‘‘(ii) lead to fraud, waste, or abuse, or *impede innovations and advancements* in health information access, exchange, and use, including care delivery enabled by health information technology.

Proposed Rule

- 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 or 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)*

ONC examples in Background. Too broad or too narrow? Consistent with congressional intent?

Practices: Draft* Discussion Points

- The definition of *interoperability elements* is very broad (beyond certified health IT) and interacts with the identified information blocking practices and actors (and other aspects of the information blocking requirements) to create a very broad and complex web of compliance risk.
- Although part of the Cures statute, the term "likely" in the regulatory definition of information blocking, without a commonly understood definition or one in the proposed rule is problematic.
  - It could lead to an ongoing a large number of commercially motivated allegations of information blocking, even without any actual blocking.
  - Actions and capabilities associated with patient matching might trigger the "likely" level of risk.
  - ONC should define "likely" as xxx.
- There is a need to allow for due diligence as distinct from simply delaying access and such diligence should not need an exception (e.g., the security exception) to avoid implicating or being judged as information blocking. The need to vet external locations of exchange includes but is not limited to apps.
  - In lieu of a focus on "vetting" of apps and other points of exchange, CARIN Alliance suggest a focus on apps needing to be "centrally registered" by an EHR or a health plan. This approach allows a light 'vetting' process of the app but also allows the app to gain access to all client end points following registration without providers needing or wanting to vert very app. https://www.carinalliance.com/wp-content/uploads/2019/02/CARIN_Private-and-Secure-Consumer-Directed-Exchange_021019.pdf
- The focus on non-standard implementations, combined with the broad definitions of *actors*, could pose challenges for certain organization, such as clinical registries, which have historically needed some non-standard implementations to achieve their intended purpose.
- There should be "safe harbor"-type provisions for some *practices* without the need to use an exception with all of its specificity.

*Not reviewed by the workgroup

Information Blocking: "Reasonable and Necessary" Exceptions

- If *practice* satisfies one or more exceptions, *actor* would not be treated as *information blocking* and not subject to penalties and disincentives
  - Most exceptions apply to all actors, unless otherwise indicated
- Consistent themes across exceptions (e.g., pro-competitive, consistent, non-discriminatory, policies in place and documented compliance with these policies)
- *Must generally meet all elements at all relevant times to satisfy an exception for each practice where an exception is claimed*
  - Rather than "substantial compliance" (e.g., HIPAA)
- The actor has the burden of proving compliance with the exception in the event of an investigation

Exception: Preventing Harm

- An actor may engage in practices that are reasonable and necessary to prevent *harm* to a patient or another person
- The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of harm (special focus on physical harm) to a patient or another person
- The practice must implement an *organizational policy* that meets certain requirements *or* must be based on an *individualized assessment of the risk in each case*

42 CFR Part 2 and ability to isolate records that could lead to harm (e.g., in notes).
Is the focus on physical harm appropriate?

Preventing Harm: Draft* Discussion Points

- ONC should be explicit in recognizing the need for deference to other state and federal laws (e.g., 42 CFR Part 2), including consideration of implications from the recently enacted Support Act
- The proposed burden of proof is unreasonable and the need to demonstrate that a policy is sufficiently tailored is likely to create a costly compliance burden
- ONC and OCR must rapidly develop detailed guidance for the field, especially in the absence of a body of case law that can guide compliance
- Will available technology enable actors, such as providers, to document compliance with specific exceptions and their detailed components, including “and” and “or” scenarios. Will compliance tracking technology need to be validated?

*Not reviewed by the workgroup

Exception: Promoting the Privacy of Electronic Health Information

- An actor may engage in practices that protect the privacy of EHI
- An actor must satisfy *at least one of four* discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices:
  1. Practices that satisfy preconditions prescribed by privacy laws;
  2. Certain practices not regulated by HIPAA but that implement documented and transparent privacy policies;
  3. Denial of access practices that are specifically permitted under HIPAA; or
  4. Practices that give effect to an individual's privacy preferences.
- Actors need not provide access, exchange, or use of EHI in a manner not permitted under the HIPAA Privacy Rule
- General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a *consistent and non-discriminatory manner*

Are non-HIPAA entities sufficiently addressed?
Organizational policies (some could be information blocking practice; others could enable exception)

Protecting Privacy: Draft* Discussion Points

- Despite the OCR guidance on the HIPAA right of access and apps, there is a broad view that providers and developers will feel a need and obligation for some due diligence regarding apps and points of exchange.
  - A recent 2019 Manatt and eHealth Initiative Issue Brief *Risky Business? Sharing Data with Entities Not Covered by HIPAA* highlights existing international , federal and state laws, regulation and guidance and the highly complex and confusing environment that healthcare-related organizations face with respect to privacy and security related rights and obligations.
- ONC needs to be more realistic about the complexities and challenges of separating out 42 CFR Part 2 data from other EHI, especially but not only when the information is contained in clinical notes.
- There are important overlaps between privacy and security that must be recognized. There is concern that the proposed exceptions do not sufficiently recognize the kinds of bad actors that are present in the environment for example, organizations that employ security-related attacks on other organizations vs. those that may have received authorization to access data but may collect more than authorized or use the information in unauthorized ways. It is essential that the exception enables actors to address the range of such security threats, including those posed by state actors.

*Not reviewed by the workgroup

Exception: Promoting the Security of Electronic Health Information

- An actor may implement measures to promote the security of EHI
  - The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI
  - The practice must be tailored to specific security risks and must be implemented in a consistent and non-discriminatory manner
  - The practice must implement an organizational security policy that meets certain requirements or must be based on an individualized determination regarding the risk and response in each case

Are non-HIPAA entities sufficiently addressed?
Organizational policies (some could be information blocking practice; others could enable exception)

Protecting Security: Draft* Discussion Points

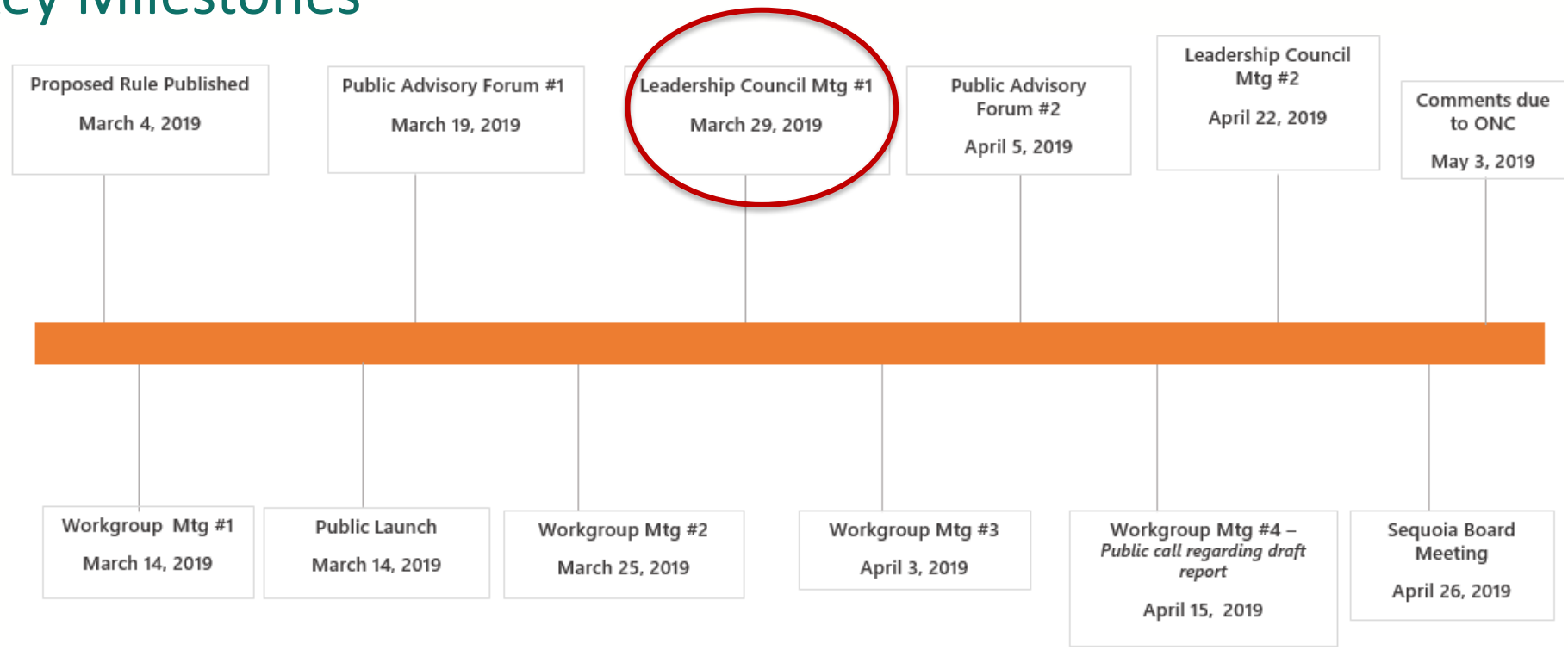
- APIs employed using appropriate standards and technologies and operational best practices, such as those developed by the CARIN Alliance, can be very secure and indeed sometimes more secure than types of legacy exchange. In the final rule, ONC should be clear on this point as well as the necessary technologies and practice to achieve such security.
- ONC should confirm that cross-organizational sharing of security information, for example a state-sponsored or other "bad actor" is permissible and does not either implicate information blocking or falls within the indicated exception.
- ONC should confirm that an organization can use security policies that exceed what is required by law or regulation based on their assessment of the threat environment, without violating this exception.
- ONC should recognize the valid need to allow for due diligence as distinct from simply delaying access and such due diligence should not need the security exception to avoid implicating or being judged as engaged in information blocking. The need for vetting of external locations of exchange includes but is not limited to apps.
- Despite OCR guidance on the HIPAA right of access and apps, there is a broad view that providers and developers will feel and need and obligation for some level of due diligence regarding apps and points of exchange.
  - A recent 2019 Manatt and eHealth Initiative Issue Brief *Risky Business? Sharing Data with Entities Not Covered by HIPAA* highlights existing international , federal and state laws, regulation and guidance and the highly complex and confusing environment that healthcare-related organizations face with respect to privacy and security related rights and obligations

*Not reviewed by the workgroup

Leadership Council Feedback on Initial Workgroup Discussions

Milestones/Timeline

Key Milestones



Confirmed Times and Registration for Leadership Council & Public Calls will be posted at https://sequoiaproject.org/interoperability-matters/information-blocking-workgroup-public-advisory-forum/

Recommendations from the Leadership Council for Cooperative Next Steps

the sequoia project

Interoperability Matters

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