



Information Blocking and You

Interoperability Matters

3/19/2019

Agenda

- Welcome and Introductions
- Context
 - Interoperability Matters
 - Information Blocking Workgroup
- Washington, DC Update
- Information Blocking Overview
- Public Input

The Sequoia Project Team

Lindsay Austin and Chris Baxter, 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

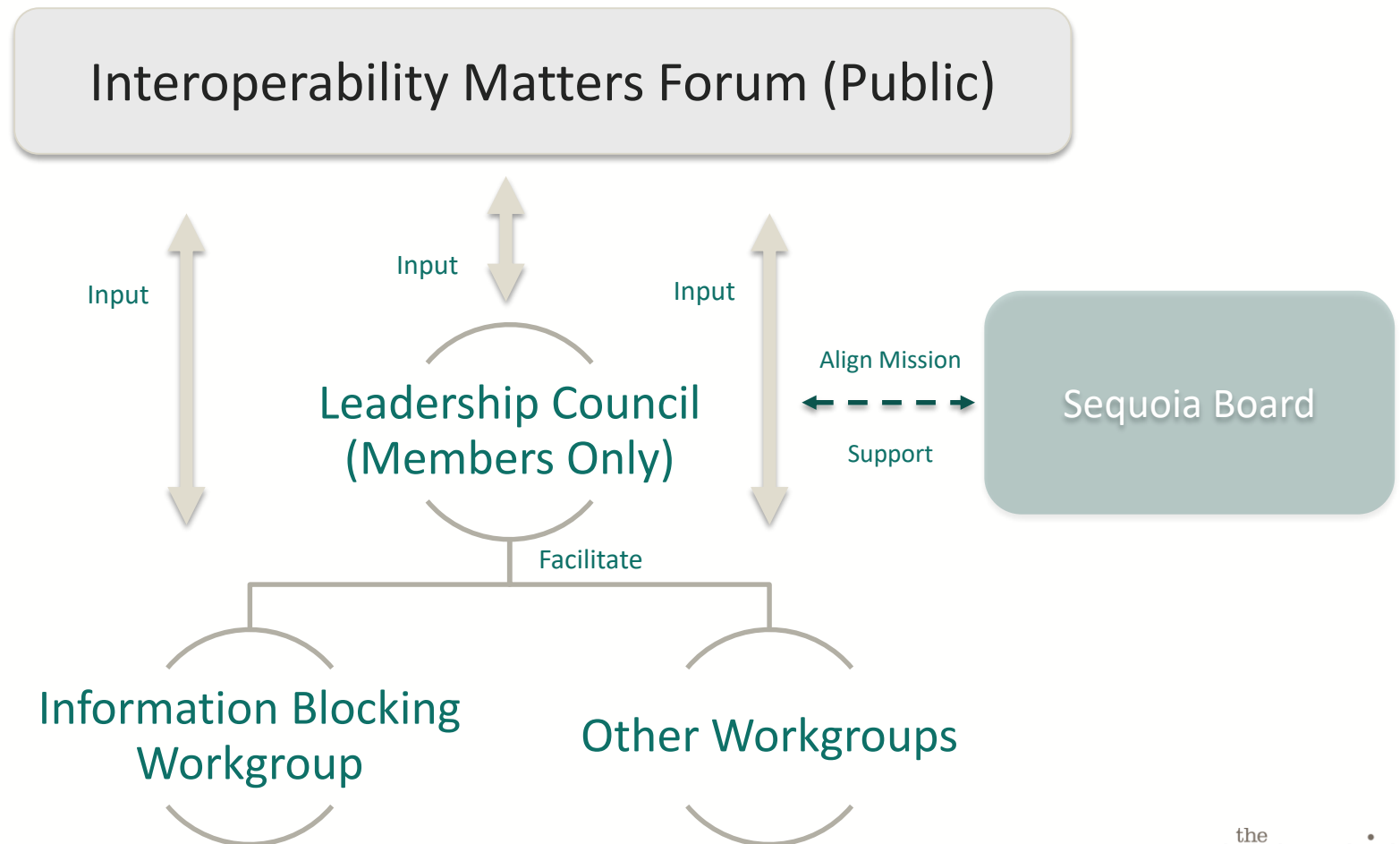


Interoperability Matters

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 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



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

Workgroup Representatives

Associations and Orgs - health IT community

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

- Dave Cassel, Carequality
- 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
- Jodi Daniel, Crowell & Moring, LLP*
- Josh Mandel, Microsoft

Payers

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

Public Health

- John Loonsk, Johns Hopkins University

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

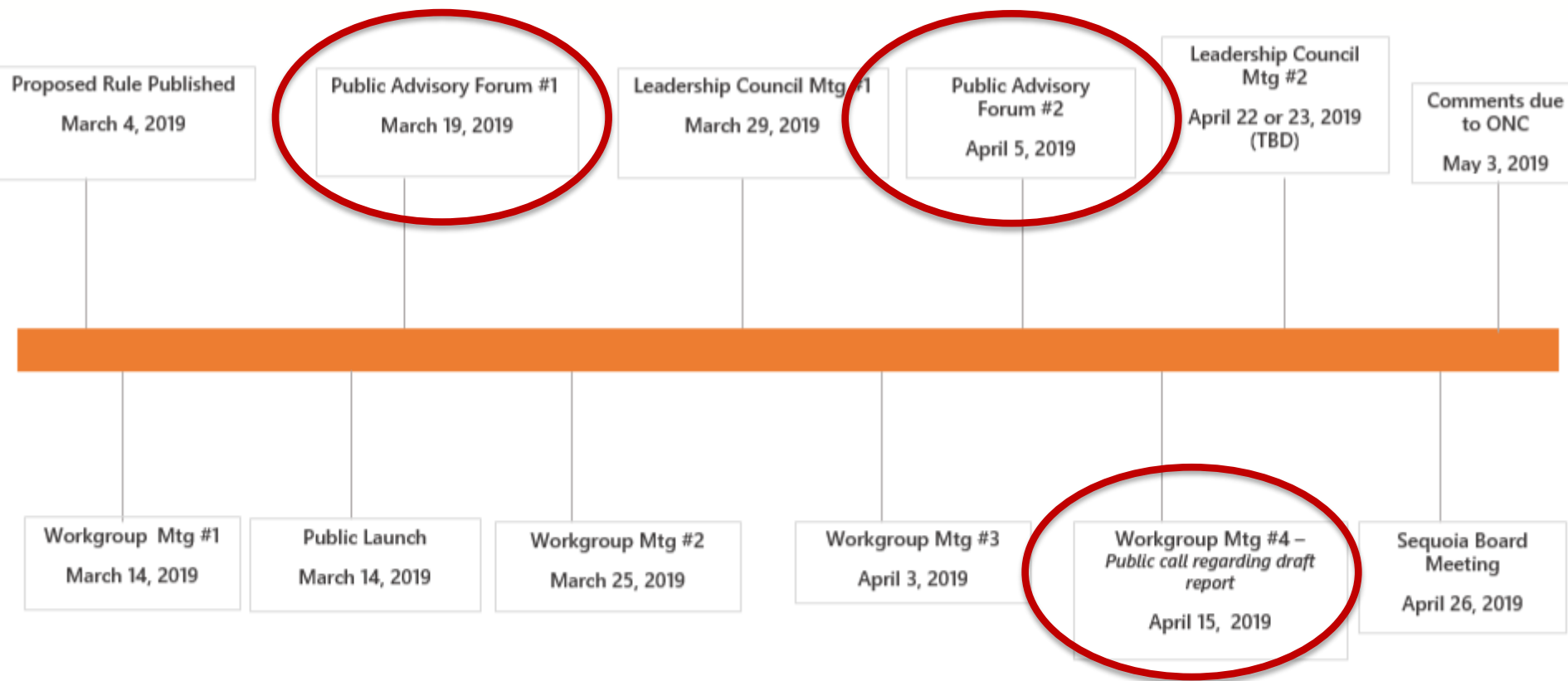
**Invited*

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
<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES</p> <p>Office of the Secretary</p> <p>45 CFR Parts 170 and 171</p> <p>RIN 0955-AA01</p> <p>21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program</p> <p>AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).</p> <p>ACTION: Proposed rule.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>• 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.</p> <p>• 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,</p>	<p>Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.</p> <p>• 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.)</p> <p>• 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.</p> <p>• 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</p>
	<p>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.</p> <p>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).</p> <p>FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202-690-7151.</p> <p>SUPPLEMENTARY INFORMATION:</p> <p>Table of Contents</p> <p>I. Executive Summary</p> <p>A. Purpose of Regulatory Action</p> <p>B. Summary of Major Provisions and Clarifications</p> <p>1. Deregulatory Actions for Previous Rulemakings</p> <p>2. Updates to the 2015 Edition Certification Criteria</p> <p>A. Adoption of the United States Core Data for Interoperability as a Standard</p> <p>B. Electronic Prescribing</p> <p>C. Clinical Quality Measures—Report</p> <p>D. Electronic Health Information Export</p> <p>E. Application Programming Interfaces</p> <p>F. Privacy and Security Transparency</p> <p>G. Data Segmentation for Privacy and Consent Management</p> <p>H. Modifications to the ONC Health IT Certification Program</p> <p>4. Health IT for the Care Continuum</p> <p>5. Conditions and Maintenance of Certification</p> <p>6. Information Blocking</p> <p>C. Costs and Benefits</p> <p>II. Background</p> <p>A. Statutory Basis</p> <p>1. Standards, Implementation Specifications, and Certification Criteria</p> <p>2. Health IT Certification Program(s)</p> <p>B. Regulatory History</p> <p>1. Standards, Implementation Specifications, and Certification Criteria Rule</p> <p>2. ONC Health IT Certification Program Rule</p> <p>III. Deregulatory Actions for Previous Rulemakings</p> <p>A. Background</p> <p>1. History of Burden Reduction and Regulatory Flexibility</p> <p>2. Executive Orders 13771 and 13777</p>

Key Milestones



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



Washington, DC Update

Chris Baxter, Troutman Sanders Strategies

Senate HELP Hearing

- Cures Rules Hearing – March 26, 2019 (10 am ET)
- Private Sector Stakeholder Panel (no government)
 - Payer
 - Vendor
 - 3rd Party App
 - Health System
 - Provider
 - Patient or Patient Representative
- 2nd Panel with Governmental Stakeholders to follow - TBD



Information Blocking Proposed Rule: Overview

Interoperability Defined §170.102

Interoperability is, with respect to health information technology, such health information technology that –

- (i) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- (ii) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and
- (iii) *Does not constitute information blocking as defined in § 171.103 of this subchapter.*

Information Blocking Defined: 21st Century Cures

SEC. 3022. INFORMATION BLOCKING. “(a) DEFINITION.— “(1) IN GENERAL.—In this section, the term ‘information blocking’ means a practice that— “(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and “(B)(i) if conducted by a health information technology developer, exchange, or 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 “(ii) 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.

(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include— “(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; and “(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.

(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

Information Blocking Defined

- 21st Century Cures: summary definition
 - *A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information*
- ONC follows Cures, taking a very broad view of the definition and mitigating with “reasonable and necessary” exceptions
- The Information Blocking provisions (and most new Conditions of Certification) are implemented on the *effective date* of the Final Rule: two month after publication
 - Other proposed rule provisions have somewhat later dates, for example new API certification criteria take effect 24 months after the effective date (development and provider implementation completed)

Information Blocking Defined: ONC Proposed Rule

§ 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.

Information Blocking: Key Definitions §171.102

- *Access*: the ability or means necessary to make EHI available for use, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained
- *Exchange*: the ability for electronic health information to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used
- *Use*: the ability of health IT or a user of health IT to access relevant electronic health information; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose

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 the 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 the functional elements of the technology, including for the purpose of developing compatible technologies that incorporate or use the functional elements.
3. Any technology or service that may be required to enable the 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

Note: Interoperability element is a key concept of API and Information Blocking provisions, for example relative to licensing

Electronic Health Information Defined §171.102

- Electronic protected health information (defined in HIPAA), and any other information that:
 - Identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
 - Is transmitted by or maintained in electronic media (defined in 45 CFR 160.103) that;
 - Relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
- Not limited to information created or received by a provider
- Does not include 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

Actors Defined §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

Information Blocking: Exceptions

- Section 4004 of Cures authorizes HHS Secretary to identify *reasonable and necessary* activities that are not information blocking
- ONC has identified 7 categories of blocking that would be reasonable and necessary, *if certain conditions are met* (45 CFR 171.201–207)
- If actions of an *actor* (health care provider, health IT developer, or health information exchange or network) *satisfy one or more exception*, these *would not be treated as information blocking* and therefore not subject to civil penalties and other disincentives
 - Most exceptions apply to all actors, unless otherwise indicated
- ONC applies Cures definitions or establishes definitions by regulation

ONC Policy Considerations for Exceptions

1. Each is limited to certain *activities that clearly advance the aims of the information blocking provision*
2. Each addresses a significant *risk that regulated actors will not engage in these beneficial activities because of uncertainty* concerning the breadth or applicability of the information blocking provision
3. Each is subject to *strict conditions to ensure that it is limited to activities that are reasonable and necessary*

Exceptions §171.201

- 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
- 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*

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*

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

Exception: Recovering Costs Reasonably Incurred

- An actor may recover costs that it reasonably incurs, in providing access, exchange, or use of EHI
- Fees must be:
 - charged on the basis of *objective and verifiable criteria uniformly applied* to all similarly situated persons and requests;
 - *related to the costs* of providing access, exchange, or use; and
 - *reasonably allocated among all customers* that use the product/service
 - Must not be based in any part on whether requestor is a *competitor*, potential competitor, or will be using EHI to facilitate competition with the actor; and
 - Must not be based on *sales, profit, revenue*, or other value that the requestor derives or may derive *that exceed the actor's reasonable costs*
- Fees must not be based on *anti-competitive* or other impermissible criteria
- Certain costs would be excluded from this exception, such as costs that are *speculative or subjective* or *associated with electronic access by an individual to their EHI*

Exception: Responding to Requests that are Infeasible

- An actor may decline to provide access, exchange, or use of EHI in a manner that is *infeasible*
- Complying with the request must impose a *substantial burden on the actor that is unreasonable under the circumstances* (taking into account the cost to the actor, actor's resources, etc.)
- The actor must *timely respond* to infeasible requests

Exception: Licensing Interoperability Elements on Reasonable and Non-Discriminatory Terms

- An actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on *reasonable and non-discriminatory terms (RAND)*
 - RAND terms often used by SDOs
- The license can impose a *reasonable royalty* but *must include appropriate rights* so that the licensee can develop, market, and/or enable the use of interoperable products and services
- License terms must be based on *objective and verifiable criteria* that are *uniformly applied and must not be based on impermissible criteria*, such as whether the requestor is a potential competitor

Exception: Maintaining and Improving Health IT Performance

- An actor may make health IT under its control temporarily unavailable to perform maintenance or improvements to the health IT
- The actor to whom health IT is provided must agree to unavailability, via service level agreement (SLA) or similar agreement or in each event
 - Obligations differ if health IT vendor or provider
- An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements

Maintenance of Certification: Information Blocking

- Per Cures, ONC proposes Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program – some relate directly or indirectly to information blocking*
 - Information Blocking*
 - Assurances *
 - Communications
 - Application Programming Interfaces (APIs)*
 - Real World Testing
 - Attestations*
 - (Future) Electronic Health Record (EHR) Reporting Criteria Submission

Note: In some cases, such as API pricing, criteria are more stringent than general information blocking provisions (e.g., fee record keeping) but must also be met to also satisfy information blocking exceptions.

Conditions of Certification: Information Blocking

§170.402

- As a *Condition of Certification* and to maintain such certification, a health IT developer must not take any action that constitutes information blocking as defined in section 4004 of the Cures Act
 - Note, in some cases, these go beyond specific certification criteria, for example, information blocking focuses on EHI rather than the USCDI and *use* includes *write* and extends beyond the proposed new API certification criteria
 - Note also that there are specific fee and transparency requirements as part of the API Condition of Certification
- This provision is subject to the 7 proposed exceptions to information blocking definition, which define reasonable and necessary activities
- No Maintenance of Certification requirements beyond ongoing compliance
- This provision and the other new Conditions and Maintenance of Certification are implemented as of the effective date of a final rule

Conditions of Certification: Application Programming Interfaces §170.404

- Apply to:
 - *API Technology Suppliers (Suppliers)* with health IT certified to any API-focused certification criteria
 - *API Data Provider:* Health care organization that deploys the API technology
 - *API User:* Persons and entities that use or create software applications that interact with API technology
- *Transparency:* ONC proposes that Suppliers make business & technical documentation necessary to interact with their APIs freely and publicly accessible
- *Permitted fees:* ONC has proposed to adopt detailed conditions that govern fees Suppliers could charge and to whom fees could be charged – detailed record keeping
- *Pro-competitive:* ONC proposes that Suppliers would have to comply with requirements to promote an open and competitive marketplace

Requests for Information

- Additional Exceptions
 - Whether ONC should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices necessary to comply with the requirements of the Common Agreement (TEFCA)—*Not a safe harbor*
 - ONC welcomes comment on any potential new exceptions for future rulemaking
- Disincentives for Health Care Providers
 - ONC asks if new disincentives or if modifying disincentives already available under HHS programs and regulations (e.g., provider attestations under incentive programs) would provide more effective deterrents

Complaint Process

- Section 3022(d)(3)(A) of PHSA directs ONC to implement a standardized process for the public to submit claims of information blocking
 - ONC intends to implement and evolve this complaint process by building on existing mechanisms, including the complaint process available at <https://www.healthit.gov/healthit-feedback>
- ONC requests comments on this approach and any alternative approaches that would best address this aspect of Cures
- ONC also requests comment on several issues in proposed rule

Interoperability Matters

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