

Agenda

- Welcome and Introductions
- Review of Workgroup Plan – Phase 2
- Actors and Other Definitions
- Next Steps
- Closing

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

The Sequoia Project Team

Lindsay Austin, Troutman Sanders Strategies

Steve Gravely, Gravely Group

Shawna Hembree, Program Manager

Mark Segal, Digital Health Policy Advisors

Dawn VanDyke, Director, Marketing Communications

Mariann Yeager, CEO

Information Blocking Workgroup Phase 2

Information Blocking Workgroup: Agenda for Future Meetings: Phase 2

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

- ✓ Meeting 1 (6/20) Review comments submitted and proposed workplan
- ❖ No July Call
- **Meeting 2 (8/2) HIE/HIN and Other Key Definitions**
- ❖ Joint Workgroup & Leadership Council (8/21) – In-person and virtual
Registration: <https://sequoiaproject.org/events/2019-in-person-meeting/>
- Meeting 3 (9/13) Information Blocking Practices
- Meeting 4 (10/11) Recovering Costs/RAND Licensing
- Meeting 5 (11/8) Compliance Plans (or review Final Rule Out)
- Meeting 6 (12/13) Review Final Rule or TBD

August Topic: HIEs/HINs and Related Key Definitions



Definitions Providing Context for Discussion of HIE and HIN

Information Blocking: ONC

§171.103 Information blocking.

Information blocking means a practice that—

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

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

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

Electronic Health Information (EHI)

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

Interoperability Element §171.102

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

Actors §171.102

Health Care Providers	Same meaning as “health care provider” at 42 U.S.C. 300jj—includes hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, emergency medical services provider, Federally qualified health center, group practice, pharmacist, pharmacy, laboratory, physician, practitioner, provider operated by, or under contract with, the IHS or by an Indian tribe, tribal organization, or urban Indian organization, rural health clinic, a covered entity ambulatory surgical center, therapist, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.
Health IT Developers of Certified Health IT	An individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health information technology (one or more) certified under the ONC Health IT Certification Program
Health Information Exchanges	Individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes
Health Information Networks	Health Information Network or HIN means an individual or entity that satisfies one or both of the following— (1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities (2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities

HITAC on HIE and HIN

HIE

- *Health Information Exchange or HIE* means: ~~a Any individual or entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the that enables access, exchange, transmittal, processing, handling or other such use of e-Electronic Health 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 policies 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.

Questions for the Workgroup

HIN Definitions

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

Questions for the Workgroup

Interoperability Elements and HIEs/HINs

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

Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion

Closing Discussion

Interoperability Matters

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