Agenda

- Welcome and Introductions
- Update on Final Report – Comments on Information Blocking
- Workplan for Phase 2
- Closing
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
- 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

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
- 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
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 Comments to ONC
Status Update

• Sequoia comment letters submitted
  – CMS Interoperability NPRM
  – ONC Cures NPRM
• Information Blocking Workgroup Findings and Recommendations
  – Accepted by Sequoia board
  – Included with public comment letters from Sequoia and Carequality
ONC received 2,013 comments, many/most on price transparency
Common themes

- Imposes a significant burden on actors
  - Complexity of exceptions
  - Ambiguity of terms
  - Cost of compliance

- Definition of Information Blocking too broad and might be struck down by courts upon review
  - “Likely” to interfere is too vague
  - ONC should provide specific examples so Actors can develop realistic compliance programs

- Definition of HIE and HIN confusing
  - Consider a single definition

- Adoption of EHI widely panned
  - ONC urged to stick with PHI

- Burden of Proof and Standard of Proof
  - Burden on Actors to prove that they did NOT info block
  - Documentation burden on providers, especially hospitals, a real concern
  - Standard too high, if you miss one part of an exception then you are outside the exception
Common themes

- Proposed Exceptions
  - Categories right but requirements too detailed and rigid
  - Some see exceptions as loopholes and others as too restrictive
  - A new “TEFCA exception” popular

- Pricing/contracting limits too restrictive, requiring too much documentation, and could distort markets; refine (e.g., focus on “basic access”)

- Should developers who are information blocking actors only be those who develop CEHRT (and subject to penalties) and conversely, should all products developed by developers of CEHRT be regulated?

- RAND creates “severe disincentive” for established developers to create new solutions
  - RAND for licensing terms needs much further study
Common recommendations

• ONC should revise NPRM and submit for second round of comments
• Effective Date should be delayed to enable Actors to modify practices
  – Suggested timelines vary from 12 months to 36 months after publication
• ONC should make clear what practices are not acceptable
• ONC should make clear the enforcement mechanism(s)
• ONC should develop a process for ongoing clarification of the rule
Our goal in providing technical assistance has been to help ensure that the final rule does not inadvertently distort competition or inhibit conduct that is affirmatively procompetitive and consumer friendly. We set out below some additional areas where the information-blocking rule and accompanying exceptions could be further refined to help minimize unintended consequences. These suggestions may help clarify the final rule so that the exceptions do not inadvertently prohibit “activities that are innocuous, or even beneficial.”

1. We acknowledge the considerable work the Department and ONC have done to identify and clarify exceptions to the information blocking prohibition; however, consider whether additional and more fully developed examples of permissible conduct, as observed in HIT and EHI use and development, could clarify safe harbors for conduct that does not harm competition or consumer welfare.

2. Consider adjusting the definition of EHI, so that it applies more narrowly to the information that is the focus of the statute, such as the information needed for patient treatment and HIT interoperability.

3. Consider (a) clarifying when market pricing is not deemed information blocking, and (b) providing additional leeway for market pricing and certain ordinary refusals (or failures) to deal under the “recovering costs reasonably incurred,” “responding to requests that are infeasible,” and the “licensing of interoperability elements on fair and reasonable terms” safe harbors.

4. Consider narrowing the proposed definition of “developers of certified HIT” so that regulatory restrictions apply to certified HIT, but not for all of its products, services, conduct, or practice, “including practices associated with any of the developer or offeror’s health IT products that have not been certified under the Program.”
HITAC: Examples of Comments to ONC

- **Recommendations 1 (HIE definition) & 2 (HIN definition):** “Substantially influences”
  - Health Information Exchange or HIE means: Any entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the access, exchange, transmittal, processing, handling, or other such use of Electronic Health Information.
  - Health Information Network or HIN means an individual or entity that satisfies one or several of the following—(1) Determines, oversees, administers, controls, or sets policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities, or (2) Provides, manages, or controls any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

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HITAC: Examples of Comments to ONC

- **Recommendation 33:** The HITAC recommends that ONC distinguish between **Basic Access** and **Value-Added** Access, Exchange, and Use . . .

- **Recommendation 35:** The HITAC recommends that ONC distinguish between IPR that are **essential** to access and IPR that allow for value-added services . .

- **Recommendation 36:** The HITAC recommends that allowed fees for basic access be on a pure direct cost recovery basis only . . .

- **Recommendation 37:** The HITAC recommends that allowed fees for access, exchange and use essential IPR be set on a RAND-basis . . .

- **Recommendation 38:** The HITAC recommends no further restrictions on permitted fees . . .
Looking Ahead

• Comment period closed **May 3 June 3**
• Final Rule likely by late Fall but timing uncertain
• Most provisions effective 60 days after final rule
• Others: 26 months after final rule (e.g., API technology criteria)
• Timing for specific provisions could change in final rule or after
• Final Rule will likely retain key provisions but with material revisions, more flexibility and relaxed timing

• Extended period of regulatory and compliance uncertainty
• Scarcity of qualified legal advice and a lack of guidance and case law to support legal interpretations
• Community will need implementation guidance to meet legislative and regulatory intent and reduce compliance uncertainty and costs
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 Definitions
- Meeting 3 (September) Information Blocking Practices
- Meeting 4 (October) Recovering Costs/RAND Licensing
- Meeting 5 (November) Compliance Plans (or review Final Rule Out)
- Meeting 6 (December) Review Final Rule or TBD
Actors and Other Definitions
Actors and Other Definitions: Findings

§171.102

- The definition of an *actor* is critical because it exposes organizations to penalties and the regulatory implications of defined *practices and exceptions*.
- The proposed definition of an *HIN* is too broad and could include organizations that are not networks; it should be more narrowly focused:
  - For example, health plans, technology companies that handle *EHI*, and standards developing organizations (SDOs) or organizations that develop recommended interoperability polices are not networks and could, inappropriately, be included in the proposed definition.
  - Should receipt of health IT incentive program payments or federal stimulus payments be a determinant of whether an organization is an HIE or an HIN?
- The definition of an *HIE* includes *individuals*, which is difficult to understand, and, as with the *HIN* definition, could sweep in individuals or organizations that are not actually HIEs.
- The distinction between HIEs and HINs is unclear; HIEs should be viewed as a subset of HINs; ONC should therefore consider combining the two types of actors into one combined definition.
- The HIT *developer* definition needs more clarity on whether its application includes all *interoperability elements* under the control of the developer.
  - In addition, the definition is too broad as it could bring in companies that only have one product certified against one or a very few criteria, for example a quality reporting module.
  - The definition would also seem to inappropriately include organizations like value-added resellers in its focus on “offers” certified health IT.
- ONC should consider defining EHI to equal PHI as defined by HIPAA.
Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion
Information Blocking Practices
Practices: Findings
§171.103 and p. 76165

• 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 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 “highly probable,” backed up with examples of actual information blocking.

• 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 (e.g. networks).
  – In lieu of a focus on “vetting” of apps and other points of exchange by providers, CARIN Alliance suggests 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 vet every app. [https://www.carinalliance.com/wp-content/uploads/2019/02/CARIN_Private-and-Secure-Consumer-Directed-Exchange_021019.pdf](https://www.carinalliance.com/wp-content/uploads/2019/02/CARIN_Private-and-Secure-Consumer-Directed-Exchange_021019.pdf)
  – It would be desirable if there can be a central point where apps are certified/vetted to achieve efficiencies for plans/providers/Vendors/app developers. If organizations want to do other vetting, that would be permitted of course, but at minimum CMS and ONC should release a White List for apps that they have vetted, and preferably also a Black List from the FTC if there is not a full fledged certification process. There is concern from some participants that being simply “registered” with a plan will not determine if it is a legitimate request, from a legitimate organization, with a legitimate scope of data elements.
Practices: Findings
§171.103 and p. 76165

• The focus on non-standard implementations, combined with the broad definitions of actors, could pose challenges for certain organizations, such as clinical registries, which have historically needed some non-standard implementations to achieve their intended purpose. In addition, we ask ONC to provide additional examples of non-standard implementations beyond those on p. 7521, for when applicable adopted standards exist and when they do not.

• There should be “safe harbor” provisions for some practices without the need to use an exception with all of its specificity.

• The nature of this rule and the underlying issue being addressed is leading ONC to assume actors have bad intent, and to err on the side of ensuring that there are no loopholes for these bad actors to exploit. This approach is understandable, but it casts such a wide net that there is a strong chance of collateral damage and pulling in those who are acting in good faith. It should be possible to relax some of the language in the practices and exceptions (e.g., “all things at all times and if no alternatives”), perhaps language that references acting in good faith and an allowance for “one off” cases in a gray area.
Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion
Recovering Costs/RAND Licensing
Recovering Costs Reasonably Incurred: Findings
§171.204

• There was strong support for ONC's proposal to provide free API access to an individual who requests access to their EHI through a consumer-facing application and ONC should consider whether this approach could be extended to public health access.

• There were varying views regarding prohibition of fees for patient access:
  – Some noted that prohibition on any fees that do not meet this very detailed exception is too complex (both preamble and regulatory text) and interferes too much with market operations and could reduce investment in needed interoperability solutions. They suggest that ONC revise the exception to shift from an emphasis on cost recovery to a focus on the shared goal, central to 21st Century Cures, that pricing should not be a deterrent to information sharing.
  – Some also were concerned with the breadth of the prohibition on fees “based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual’s electronic health information,” particularly the reference to “designees.” They noted that data accessed in this way by commercial “designees” (e.g., apps) has economic value with costs associated with its provision. Prohibiting any such fees to designees (as opposed to the individual) as part of the information blocking provision, beyond API certification requirements, could reduce investment in interoperability capabilities and overall availability of information. In addition, this issue has important interaction effects with the companion CMS interoperability proposed rule if payers, who are required and encouraged to create APIs are unable to recover costs because they have been defined as HIEs or HINs as part of this rule.

• There was concern with a high burden for hospitals to comply with this exception.
Recovering Costs Reasonably Incurred: Findings
§171.204

• We ask ONC to clarify what individuals and entities are subject to the prohibition of fees for individual access and how to determine if an entity is actually an individual’s designee for data sharing. More generally we ask ONC to clarify whether consent to share information to be interpreted as equivalent to actual patient direction to share?

• Many terms in this exception are subjective (e.g., “reasonable). We ask ONC to provide clear definitions in the final rule and associated guidance.
  — In particular, we ask ONC to provide more guidance on the allowance for “reasonable profit” in the preamble (p. 7538) and to explicitly include such an allowance in the regulatory text.

• ONC states that the method to recover costs “[m]ust not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of electronic health information, including the secondary use of such information, that exceeds the actor’s reasonable costs for providing access, exchange, or use of electronic health information.” The preamble (p. 7539) further states that “such revenue-sharing or profit-sharing arrangements would only be acceptable and covered by the exception if such arrangements are designed to provide an alternative way to recover the costs reasonably incurred for providing services.” The term “alternative” is confusing and could be read to imply that this method is an alternate to another simultaneously offered method of cost recovery, which we do not believe is ONC’s intent; we ask ONC to clarify.
Recovering Costs Reasonably Incurred: Findings
§171.204

• The disallowance for costs that are “due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using electronic health information” requires further clarification. In particular, ONC should recognize that there are often multiple actors and actor-types involved in an implementation. A given actor could face higher costs as a result of non-standard implementations by another actor (e.g., a provider, a developer or vice versa). Such costs incurred as a result of non-standard design or implementation by another actor should be able to be reflected in fees.

• This exception should be expanded to clarify that costs associated with research, including costs from non-standard implementations due to research needs, should be able to be reflected in fees.

• There was interest and uncertainty as to how rapidly useful pricing information can be included in this exception.
Reasonable and Non-Discriminatory Terms (RAND) Licensing: Findings §171.206

• Overall, we ask ONC to simplify this exception and its scope and to provide more guidance on RAND licensing and its implementation.

• We request that ONC address the potential for unintended consequences; for example, some health IT delivery models might have fees eligible for the RAND licensing exception and others would only eligible for 171.204, with the potential for higher net financial returns under one model or the other, a preference that is not intended (and should not be) as a matter of public policy.

• The preamble discussion of this exception is complex and will require very technical and fact-specific steps by actors, including establishment of “reasonable” royalties.

• We ask ONC to consider the combined implications and timing to assess feasibility, licensing implications and enter a negotiation for licensing within a 10-day timeframe.
Reasonable and Non-Discriminatory Terms (RAND) Licensing: Findings §171.206

• In addition, given the extensive use of licenses as one element of commercial health IT software offerings, we ask ONC to clarify which software licenses would need to (be revised to) meet this exception to avoid information blocking (i.e., will all software licenses need to be converted to RAND terms or only those that focus on specific intellectual property rights, and in what timeframe?). For example, would licenses for EHRs presented to providers be subject to this provision or only licenses for specific IP (e.g., code sets) or APIs licensed by an EHR developer to an application developer? We also ask ONC to recognize that this exception, if it requires changes to virtually all health IT software licenses, is likely to have far reaching and very disruptive impacts on the market for health IT software, including a high compliance and documentation burden.

• We ask ONC to clarify its definition of “royalty” and which fees associated with licenses software would be consider a royalty and which would not, and hence only eligible for the exception at 171.204.
Reasonable and Non-Discriminatory Terms (RAND) Licensing: Findings §171.206

- We ask ONC to clarify whether, in all cases, fees that might be associated with software are also eligible for the alternate exception under 171.204. The preamble (p. 7549) states that “[f]inally, the actor must not condition the use of interoperability elements one requirement or agreement to pay a fee of any kind whatsoever unless the fee meets either the narrowly crafted condition to this exception for a reasonable royalty, or, alternatively, the fee satisfies the separate exception proposed in § 171.204, which permits the recovery of certain costs reasonably incurred”.

- We also ask ONC to clarify whether an actor that licenses an interoperability element, and chooses to use the exception at 171.204 for fees, would also need to use this exception, as there are many non-monetary aspects of this exception.

- We ask ONC to address an actor’s obligation to license intellectual property that they do not yet have and to clarify that inability to honor such a request could be met by the feasibility exception and would not require use of this one as well.
Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion
Compliance Plans
Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion
Closing Discussion
Interoperability Matters

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