



# Information Blocking Workgroup Meeting #3

## Interoperability Matters

*4/3/2019*

# Agenda

- Welcome and Introductions
- Exceptions
  4. Recovering costs reasonably incurred
  5. Declining to provide access, exchange, or use of EHI if request is infeasible
  6. Licensing technologies or other interoperability elements
  7. Making health IT unavailable to perform maintenance or improvements
- Conditions & Maintenance of Certification: Information Blocking
- RFIs: disincentives for providers and price transparency
- Complaints and enforcement
- Next Steps

# 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

## Rules of the Road

- We want to hear from you!
- Let's focus on highest priority points and themes
- We encourage use of chat during the meeting to make points and we will capture the chat logs
- Send us your thoughts between meetings
  - [interopmatters@sequoiaproject.org](mailto:interopmatters@sequoiaproject.org)
  - Reference “Workgroup” in message header

## 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*

Issues: Documentation? “Related” to costs vs. equal to costs? Profit – not in regulatory language?  
Unintended consequences?

# Exception: Recovering Costs Reasonably Incurred

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Types of costs to which this exception applies.* This exception is limited to the actor's costs reasonably incurred to provide access, exchange, or use of electronic health information.

(b) *Method for recovering costs.* The method by which the actor recovers its costs—

(1) Must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests;

(2) Must be reasonably related to the actor's costs of providing the type of access, exchange, or use to, or at the request of, the person or entity to whom the fee is charged;

(3) Must be reasonably allocated among all customers to whom the technology or service is supplied, or for whom the technology is supported;

(4) Must not be based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor; and

(5) Must 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.

(c) *Costs specifically excluded.* This exception does not apply to—

(1) Costs that the actor incurred 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;

(2) Costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets;

(3) Opportunity costs, except for the reasonable forward-looking cost of capital;

(4) A fee prohibited by 45 CFR 164.524(c)(4);

(5) A fee 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;

(6) A fee to perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10) of this subchapter for the purposes of switching health IT or to provide patients their electronic health information; **or**

(7) A fee to export or convert data from an EHR technology, unless such fee was agreed to in writing at the time the technology was acquired.

(d) *Compliance with the Conditions of Certification.* (1) Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the Conditions of Certification in § 170.402(a)(4) or § 170.404 of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

(2) If the actor is an API Data Provider, the actor is only permitted to charge the same fees that an API Technology Supplier is permitted to charge to recover costs consistent with the permitted fees specified in the Condition of Certification in § 170.404 of this subchapter.

# Recovering Costs : Recommendations

## 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

Likely scenarios? Too broad or too narrow?



# Exception: Responding to Requests that are Infeasible

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Request is infeasible.* (1) The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances, taking into consideration—

- (i) The type of electronic health information and the purposes for which it may be needed;
- (ii) The cost to the actor of complying with the request in the manner requested;
- (iii) The financial, technical, and other resources available to the actor;
- (iv) Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
- (v) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged;
- (vi) Whether the actor maintains electronic protected health information on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains electronic health information on behalf of the requestor or another person whose access, exchange, or use of electronic health information will be enabled or facilitated by the actor's compliance with the request;
- (vii) Whether the requestor and other relevant persons can reasonably access, exchange, or use the electronic health information from other sources or through other means; **and**
- (viii) The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.

(2) The following circumstances do not constitute a burden to the actor for purposes of this exception and shall not be considered in determining whether the actor has demonstrated that complying with a request would have been infeasible.

- (i) Providing the requested access, exchange, or use in the manner requested would have facilitated competition with the actor.
  - (ii) Providing the requested access, exchange, or use in the manner requested would have prevented the actor from charging a fee.
- (b) *Responding to requests.* The actor must timely respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements.
- (c) *Written explanation.* The actor must provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request.
- (d) *Provision of a reasonable alternative.* The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information.

# Infeasible Requests: Recommendations

## 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

Issues: Documentation? Unintended consequences? “Reasonable”? Scope of this requirement – EHRs?

# Exception: Licensing Interoperability Elements on Reasonable and Non-discriminatory Terms

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Responding to requests.* Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by:

(1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; **and**

(2) Offering an appropriate license with reasonable and non-discriminatory terms.

(b) *Reasonable and non-discriminatory terms.* The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory.

(1) *Scope of rights.* The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable.

(i) Developing products or services that are interoperable with the actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's interoperability elements to interoperate with the actor's health IT or health IT under the actor's control.

(ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users.

(iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

(2) *Reasonable royalty.* If the actor charges a royalty for the use of the interoperability elements described in paragraph (a) of this section, the royalty must be reasonable and comply with the following requirements.

(i) The royalty must be non-discriminatory, consistent with paragraph (b)(3) of this section.

(ii) The royalty must be based solely on the independent value of the actor's technology to the licensee's products, not on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using electronic health information.

(iii) If the actor has licensed the interoperability element through a standards development organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on reasonable and non-discriminatory terms, the actor may charge a royalty that is consistent with such policies.

# Exception: Licensing Interoperability Elements on Reasonable and Non-discriminatory Terms

(3) *Non-discriminatory terms.* The terms (including royalty terms) on which the actor licenses and otherwise provides the interoperability elements must be non-discriminatory and comply with the following requirements.

(i) The terms must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.

(ii) The terms must not be based in any part on—

(A) Whether the requestor or other person is a competitor, potential competitor, or will be using electronic health information obtained via the interoperability elements in a way that facilitates competition with the actor; **or**

(B) The revenue or other value the requestor may derive from access, exchange, or use of electronic health information obtained via the interoperability elements, including the secondary use of such electronic health information.

(4) *Collateral terms.* The actor must not require the licensee or its agents or contractors to do, or to agree to do, any of the following.

(i) Not compete with the actor in any product, service, or market.

(ii) Deal exclusively with the actor in any product, service, or market.

(iii) Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements.

(iv) License, grant, assign, or transfer to the actor any intellectual property of the licensee.

(v) Pay a fee of any kind whatsoever, except as described in paragraph (b)(2) of this section, unless the practice meets the requirements of the exception in § 171.204.

(5) *Non-disclosure agreement.* The actor may require a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of the actor's trade secrets, provided—

(i) The agreement states with particularity all information the actor claims as trade secrets; **and**

(ii) Such information meets the definition of a trade secret under applicable law.

(c) *Additional requirements relating to the provision of interoperability elements.* The actor must not engage in any practice that has any of the following purposes or effects.

(1) Impeding the efficient use of the interoperability elements to access, exchange, or use electronic health information for any permissible purpose.

(2) Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand.

(3) Degrading the performance or interoperability of the licensee's products or services, unless necessary to improve the actor's technology and after affording the licensee a reasonable opportunity to update its technology to maintain interoperability.

(d) *Compliance with conditions of certification.* Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the conditions of certification in §§ 170.402, 170.403, or 170.404 of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

# RAND Licensing: Recommendations

# 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

How practical will notification be for unplanned downtime. Can SLAs meet this requirement?

# Exception: Maintaining and Improving Health IT Performance

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Maintenance and improvements to health IT.* An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is—

(1) For a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable;

(2) Implemented in a consistent and non-discriminatory manner; **and**

(3) If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, *agreed to* by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT.

(b) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

(c) *Security-related practices.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.



# Health IT Performance: Recommendations

# 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.*

# Information Blocking/Certification: Recommendations

# 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

Any new exceptions needed? Additional provider disincentives?

# RFIs: Recommendations

# Complaint Process and Enforcement

- 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
- Enforcement primarily by ONC and OIG (limited role for ACBs)

Is complaint and enforcement process clear?

# Complaint Process: Recommendations

## Final Thoughts and Next Steps

- Next meeting is April 15 with public invited to listen and comment at end
- There is also another public forum on April 5
- Please send any follow-up thoughts on topics addressed by April 5 if possible
  - [interopmatters@sequoiaproject.org](mailto:interopmatters@sequoiaproject.org)
  - Reference “Workgroup” in message header



# Interoperability Matters

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