



## Meeting Notes

### Health Information Technology Advisory Committee

#### Information Blocking Task Force

#### Workgroup 2: Exceptions

March 22 2019, 2:30 p.m. – 4:30 p.m. ET

Virtual

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The March 22, 2019, meeting of the Information Blocking Task Force Workgroup 2: Exceptions of the Health IT Advisory Committee (HITAC) was called to order at 2:30 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

**Lauren Richie** conducted roll call.

### Roll Call

#### MEMBERS IN ATTENDANCE

**Andrew Truscott**, Co-Chair, Accenture  
Anil Jain, Member, IBM Watson Health  
Arien Malec, Member, Change Healthcare

#### MEMBERS NOT IN ATTENDANCE

**Michael Adcock**, Co-Chair, Individual  
Valerie Grey, Member, New York eHealth Collaborative  
Steven Lane, Member, Sutter Health

#### ONC STAFF

Mark Knee, Staff Lead  
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer  
Lauren Wu, ONC SME

**Lauren Richie** called the meeting to order and turned the meeting over to Andy Truscott, co-chair.

**Andy Truscott** turned the meeting over to Mark Knee to provide additional information regarding the thinking that went into the information blocking exceptions in the notice of proposed rulemaking (NPRM).

### Information Blocking – Exceptions

**Mark Knee** reviewed a presentation on the information blocking exceptions.

#### Overview of Exceptions

- The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.



- If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.
- Proposed exceptions to the information blocking definition
  - 171.201 — Preventing harm
  - 171.202 — Promoting the privacy of EHI
  - 171.203 — Promoting the security of EHI
  - 171.204 — Recovering costs reasonably incurred
  - 171.205 — Responding to requests that are infeasible
  - 171.206 — Licensing of interoperability elements on reasonable and non-discriminatory terms
  - 171.207 — Maintaining and improving health IT performance

### Exception: Recovering Costs Reasonably Incurred

- Under the proposed exception, it will not be information blocking for an actor to recover its reasonable costs of enabling access, exchange, or use of EHI. The proposed exception does not prescribe the amount of fees that can be charged, but imposes conditions to ensure that an actor's method for recovering costs is reasonable and nondiscriminatory.
- To qualify for this exception, an actor must ensure that:
  - Its method for recovering costs complies with certain conditions
  - It is not seeking to recover costs that are specifically excluded
  - It complies with the Conditions of Certification at § 170.402(a)(4) or § 170.404, and the fee limitations imposed on health IT developers of certified health IT, if applicable
- Objective
  - Enable actors to recover the costs reasonably incurred to develop technologies and provide services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.
  - Would not prevent an actor from making a profit.

**Arien Malec** questioned the definition of reasonable.

- **Mark Knee** acknowledged that profits were not explicitly called out in the regulation text. As far as what is reasonable, there are examples provided in the preamble of what could constitute reasonable. Reasonableness is a standard used in law.
- Conditions Applicable to Cost Recovery Method
- The method by which an actor recovers costs:
  - Must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests;
  - 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 to whom the fee is charged;
  - Must be reasonably allocated among all customers to whom the technology is supplied, or for whom the technology is supported;



- Must not be based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the data in a way that facilitates competition with the actor; and
- Must not be based on the sales, profit, revenue, or other value that the requestor or other persons may derive from the access, exchange, or use EHI that exceeds the actor's reasonable costs for providing access, exchange, or use of EHI.
- Costs Specifically Excluded:
  - Costs that are 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 EHI.
  - Costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets.
  - Opportunity costs, except for the reasonable forward-looking cost of capital.
  - A fee prohibited by 45 CFR 164.524(c)(4).
  - A fee based in any part on an individual's electronic access to their EHI.
  - A fee to perform an export of EHI via the capability of health IT certified to 45 CFR 170.315(b)(10) for the purposes of switching health IT or to provide patients with their EHI.
  - 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. Exception: Recovering Costs Reasonably Incurred C

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

- Under the proposed exception, it will not be information blocking for an actor to interfere with the access, exchange, or use of EHI by limiting access to an interoperability element, so long as the interoperability element is available for use by those that need it on reasonable and non-discriminatory (RAND) terms.
- To qualify for this exception, an actor must demonstrate that it:
  - Timely responded to persons requesting to license or use an interoperability element
  - Offered an appropriate license with RAND terms
  - Met additional requirements relating to the provision of interoperability elements
  - Complied with relevant conditions of certification
- Objective
  - An actor that controls a functional element of health IT that could be used to access, exchange, or use EHI should make that interoperability element available to others that need it, but can impose RAND terms when doing so.
  - Complying with this exception would not prevent an actor from making a profit.
- 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:
  - Negotiating with the requestor in a RAND fashion to identify the interoperability elements that are needed; and
  - Offering an appropriate license with RAND terms.
- A RAND license provides all rights necessary to access and use interoperability elements for the purpose of (as applicable):



- 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 such health IT;
- Marketing, offering, and distributing interoperable products or services to potential customers and users; and
- Enabling the use of interoperable products or services in production environments.
- Imposes no more than a reasonable royalty for use of the interoperability elements.
- Contains terms that are objective, verifiable, and uniformly applied, and are not based on whether the requestor is a competitor or the revenue the requestor may derive from the EHI obtained via the interoperability element.
- Must not contain collateral terms that are anti-competitive.
- Must not contain non-disclosure obligations that are broader than necessary to protect trade secrets.

**Arien Malec** questioned if the NPRM has a perspective on licensing that is standards-essential or essential for access, exchange, and use?

- **Mark Knee** encouraged the group to think through real-life scenarios. If the task force thinks ONC missed the mark or was unclear with the proposals, ONC encourages the task force to submit recommendations for improvement.

#### Additional Requirements

- To qualify for this exception, the actor must not engage in any practice that has any of the following purposes or effects:
  - Impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any purpose for which a person is authorized, permitted, or required to access, exchange, or use the EHI under applicable law;
  - Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand; or
  - Making changes to interoperability elements or health IT that “break” compatibility or otherwise degrade the performance of the licensee's compatible technologies or services unless the actor has afforded the licensee a reasonable opportunity to update its technologies or services to maintain interoperability.

**Arien Malec** suggested making comments that tailor the requirements more narrowly to the classes of activities that are more/less problematic.

The workgroup members discussed several different scenarios to talk through how this would be applied. This helped to provide a better understanding for members as to how this would actually be applied.

## Additional Exceptions

### Request for Information on New Exceptions

**Mark Knee** turned the conversation over to Andy Truscott.

**Andy Truscott** asked the group if there were additional exceptions to be considered.

**Arien Malec** suggested a policy framework that allows data to flow.



There was a bit of discussion by the group around business associate agreements (BAAs), but in the end, it was decided that there should be an additional specification in the NPRM and BAAs should not be added as an additional exception.

The workgroup questioned whether there is an exception in place that would cover national security issues. They did not reach a conclusion and decided to further review the security exception.

The workgroup suggested that the NPRM should be more explicit around organizational policies needed to conform to the states in which consent is being sought.

## Process for Coming up with Recommendations from the Workgroup

**Andy Truscott** suggested dividing and conquering the discussion items coming out of this group into a consolidated set of recommendations. The recommendations are broken into three areas:

- Discussion – an area to capture the details of all of the discussions
- Regulatory text – recommended changes to regulatory text
- Preamble – recommended changes to preamble

**Arien Malec** noted there are definition dependencies and questioned how that issue can be reconciled.

- **Andy Truscott** suggested reviewing the definitions being discussed by Work Group 1.
- **Arien Malec** volunteered to take on the fees section. He also agreed to pull items out of the exceptions and create a separate section that will include fees that can be charged.

**Lauren Richie** opened the lines for public comment.

## Public Comment

There was no public comment.

## Next Steps and Adjourn

The next workgroup call will be on Wednesday, March 27 at 4:00 p.m. ET.

**Lauren Richie** adjourned the meeting at 4:30 p.m. ET.