



## Meeting Notes

### Health Information Technology Advisory Committee

#### Information Blocking Task Force

#### Workgroup 2: Exceptions

April 05 2019, 2:30 p.m. – 4:30 p.m. ET

Virtual

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The April 05, 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 Cassandra Hadley, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

**Cassandra Hadley** conducted roll call.

### Roll Call

#### MEMBERS IN ATTENDANCE

**Michael Adcock**, Co-Chair, Individual

**Andrew Truscott**, Co-Chair, Accenture

Valerie Grey, Member, New York eHealth Collaborative

Anil Jain, Member, IBM Watson Health

Arien Malec, Member, Change Healthcare

#### MEMBERS NOT IN ATTENDANCE

Steven Lane, Member, Sutter Health

#### ONC STAFF

Cassandra Hadley, ONC Staff Lead

Mark Knee, Staff Lead

Morris Landau, ONC SME

Lauren Wu, ONC SME

**Cassandra Hadley** turned the meeting over to Andy Truscott, co-chair.

**Andy Truscott** shared that the members have done a great job consolidating the discussions and putting together recommendations for the group. He turned it over to Anil Jain to walk through the first recommendation.

#### **171.201 Exception — Preventing harm**

**Anil Jain** presented the information he put together around this section. The group did real-time editing during the meeting which is reflected below.



## REGULATORY TEXT RECOMMENDATION

1. Modify the (a) to read “...arising from any of the following -- ” prior to subitems (1) – (3)
2. Modify (a) (1) to read “Technically corrupt (defined as data that has lost its base integrity and is no longer understandable by the system that created it) or inaccurate data accessed in a patient’s electronic health record for intent of access, exchange or use;”
3. Add a subitem (d) that the practice should be documented in the electronic health record or system recording the EHI by the appropriate user when the exception arising from using conditions (a) - (c) and must contain the reasoning and criteria used in the judgment of the user who is engaging in the practice under this Exception.
4. In (b) language appears to be confusing...the word “practice” refers to the information blocking potentially occurring under an exception. Perhaps rephrasing “If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—  
”
5. Recommend adding a subitem under (b) that existing organizational policies should be reviewed by the organization for consistency with these regulations in order to prevent confusion and undue burden to providers.
6. Recommend adding clear guidance of when this Exception should be used vs the Exceptions for Infeasibility and Maintenance.
  - **Anil Jain** agreed to do more work on this item.

## PREAMBLE TEXT RECOMMENDATION

Consider adding examples of where Exceptions related to preventing harm from corrupt or inaccurate data or incorrect patient identification may interact with the Exception related to Infeasibility.

### Request for information on new exceptions

**Arien Malec** walked through his proposed language provided below.

Contractual obligations may and often do conflict with the broad requirements for information blocking. The preamble text discussed multiple situations where contractual terms are used by Actors to restrict use of information. The preamble did not address situations where Actors are dependent on contractual terms from other parties that may conflict with information blocking provisions. As an example, Business Associates have only the data use rights that are granted under business associate agreements (BAA); these data use rights may not allow access for all permissible uses. Contractual terms that limit BA data use rights are quite common. Should counterparties not change BAA terms, BAs would be in a difficult position, forced to choose between:

- Canceling contracts, often subjecting BAs to penalties under contract, and sometimes opening BAs to information blocking enforcement
- Complying with contractual terms and risking information blocking enforcement
- Complying with information blocking provisions, while violating contracts and possibly opening up HHS Office on Civil Rights (OCR) enforcement for violating BAA terms.



Similar situations would apply for intellectual property rights (IPR) licenses (e.g., terminology sets) that may have provisions preventing information sharing with information requesters who do not have IPR grants.

## REGULATORY TEXT RECOMMENDATION

The HITAC recommends that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly clarified by ONC. The simplest solution would be to interpret the intent of Congress to preempt contractual terms that are in conflict with the 21st Century Cures Act.

**Andy Truscott** asked **Arien Malec** to review the language from workgroup 3's Communications section for consistency.

**Arien Malec** agreed to do additional homework summarizing the discussion, that these are not exceptions and ONC needs to clarify preemption.

## Complaint Process

**Valerie Grey** shared general concepts but noted that she needs more feedback from the group around enforcement and consistency.

- General recommendation that as ONC goes through the complaint process, there needs to be a component of consideration around industry standards.
- Need to be sure that ONC and the Office of the Inspector General (OIG) have agreed on the preamble and regulatory language.
  - **Mark Knee** noted that ONC and OIG have been working closely and will continue to do so moving forward.

## Request for information on disincentives for health care providers

**Arien Malec** reviewed his proposed language included below.

## DISCUSSION

The Committee believes that, while some types of problematic activities relating to information blocking are more typical of Health IT developers or other similar actors, other refusals to share data, including using overinterpretation of Health Insurance Portability and Accountability Act (HIPAA) and other privacy laws, stricter than necessary organizational policies, or concerns of patient "leakage" to competitive institutions, are more typical of provider organizations. The Committee believes that disincentives must be sufficient to discourage problematic behavior, encourage compliance, and incent providers to work with OIG and others to address and remediate problematic behavior.

## REGULATORY TEXT RECOMMENDATION

The Committee recommends that ONC work with the Centers for Medicare and Medicaid Services (CMS) to build information blocking disincentives into a broad range of CMS programs, and that ONC work with other Federal departments and agencies that contract with providers (e.g., Veterans Health Administration (VHA), Department of Defense (DoD)) to similarly build information blocking disincentives into contracting and other programs.



The Committee recommends that providers attest to comply with information blocking requirements as a part of Conditions of Participation, Conditions for Coverage, contracts, and other similar relationships, covering both fee for service (FFS), value-based care, and direct payment relationships, and that findings of information blocking by OIG, findings violations, relating to information blocking attestations, of the False Claims Act by Federal Trade Commission (FTC) , or other similar enforcement actions trigger disincentives up to and including removing organizations from participation or coverage.

**Anil Jain** commented that he is confused by what they are asking for here.

**Arien Malec** and others questioned what is included in the CMS rule. He suggested that ONC, OIG, and CMS work together to identify reasonable modifications of behavior. There should be appropriate disincentives for providers who might receive a significant portion of their revenue from government programs.

## Public Comment

There was no public comment.

## Comment in the Public Chat

**Andy Truscott:** "Data that has lost its base integrity and is no longer understandable by the system that created it."

**Mark Knee:** do you want me to add that?

**Andy Truscott:** i have done - look up

**Mark Knee:** looks like Anil just added

## Adjourn

**Cassandra Hadley** adjourned the meeting at 4:30 p.m. ET.