

# Information Blocking

## What is It and Why Do I Care?

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# Bring on the Acronyms

- **ONC:** Office of the National Coordinator of Health Information Technology
- **EHI:** Electronic Health Information
- **CEHRT:** Certified EHR Technology

# Agenda

- The 5 “W’s”: An Overview of Information Blocking
- Examples of Potential Information Blocking Activities
- The Exceptions
- Enforcement

# Understanding Information Blocking

- Who?
- What?
- Where?
- When?
- Why?

# Understanding Information Blocking

- Who?
- What?
- Where?
- When?
- **Why?**

# Why?

- 2015 Congressional study on Information Blocking
- 2016 21<sup>st</sup> Century Cures Act signed into law
- 2019 Proposed Rule
- From ONC:  
**“The rule is designed to give patients and their healthcare providers secure access to health information. It also aims to increase innovation and competition by fostering an ecosystem of new applications to provide patients with more choices in their healthcare.”**

# Understanding Information Blocking

- **Who?**
- What?
- Where?
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# Who?

## Providers

Providers as defined in the PHSA  
Different than the definition of provider under HIPAA

## Developers

Health IT developers of CEHRT...but application does not apply just to the CEHRT  
Includes conduct by entities that offer CEHRT  
Includes “Self-developers” who provide CEHRT to others  
Applies only as long as developer has CEHRT

## HIE/HIN

Controls/administers access, exchange, or use of EHI  
- Among more than two unaffiliated entities (not including the Actor) enabled to exchange with one another  
- Which exchange for TPO purposes

Defined collectively in the Information Blocking Rule as ‘Actors’



# Understanding Information Blocking

- Who?
- **What?**
- Where?
- When?
- Why?

# What?



- **INTERFERENCE**

- **INTENT**

- **NO EXCEPTION**

# What?

- A practice that is **likely to interfere** with access, exchange, or use of EHI
  - Providers must know a practice is unreasonable and likely to **interfere** with, **prevent**, or **materially discourage** or such access, exchange or use
  - Unless required by law
  - Commentary sets out suspect practices
- **Eight exceptions** to the Information Blocking provisions

# Information Blocking and HIPAA

- Terminology used in the Information Blocking Final Rule may be familiar
  - Certain terms were purposefully taken from/related to HIPAA
  - Access; Use; Designated Record Set; EHI
  - EHI is ePHI that would be in a Designated Record Set (regardless of whether actually covered by HIPAA)
- Requires a change in the way we think about disclosures
  - HIPAA: permissive disclosure and presumption of nondisclosure
  - Info Blocking: mandatory disclosure unless exception applies and presumption of disclosure
- BAAs can include standard term limiting uses and disclosures, but must not be drafted in a discriminatory manner

# Understanding Information Blocking

- Who?
- What?
- **Where?**
- When?
- Why?

# Where?

- 45 CFR §171.100-303

# Understanding Information Blocking

- Who?
- What?
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- **When?**
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# When?

- November 2, 2020
  - Compliance date
- May 2, 2022
  - Change in definition of what information must be disclosed (will discuss in the content and manner exception)



# So What Could Constitute Information Blocking?

Provides

- Delay in posting results to a portal?
- Requiring Access Agreements?

Developers

- Using nonstandard protocols?
- Only sharing among providers using vendor's software?

HIE/HIN

- Charging fees?
- Limiting transmission of EHI to participants?

# Exceptions



**PREVENTING  
HARM  
EXCEPTION**



**PRIVACY  
EXCEPTION**



**SECURITY  
EXCEPTION**

**EXCEPTIONS THAT INVOLVE**  
not fulfilling requests to access,  
exchange, or use EHI



**INFEASIBILITY  
EXCEPTION**



**HEALTH IT  
PERFORMANCE  
EXCEPTION**

# 8

**EXCEPTIONS TO THE  
INFORMATION  
BLOCKING  
PROVISION**



**LICENSING  
EXCEPTION**



**COSTS  
EXCEPTION**



**CONTENT AND  
MANNER  
EXCEPTION**

**EXCEPTIONS THAT INVOLVE**  
procedures for fulfilling requests  
to access, exchange, or use EHI

# Preventing Harm

It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

## Purpose:

recognizing that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI.

## Key Conditions:

- **reasonable belief** that the practice will substantially reduce a risk of harm
- **no broader than necessary**
- must satisfy at least one condition from each of the following categories: **type of risk, type of harm, and implementation basis**
- must give a patient **the right to request review** of an individualized determination

# Privacy

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

## Purpose:

recognizing that if an actor is permitted to provide access, exchange, or use of EHI under a privacy law, then the actor should provide that access, exchange, or use. However, an actor should not be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws.

## Sub-Exceptions:

- **Precondition not satisfied:** If an actor is required by a state or federal law to satisfy a precondition which has not been satisfied under certain circumstances.
- **Health IT developer of certified health IT not covered by HIPAA.**
- **Denial of an individual's request for their EHI consistent with the HIPAA Privacy Rule.**
- **Respecting an individual's request not to share information:** An actor may choose not to provide access, exchange, or use of an individual's EHI if doing so fulfills the wishes of the individual, provided certain conditions are met.

# Security

It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.

## Purpose:

cover all legitimate security practices by actors, but does not prescribe a maximum level of security or dictate a one-size-fits-all approach.

## Key Conditions:

- The practice must be:
  - **Directly related** to safeguarding the confidentiality, integrity, and availability of EHI;
  - **Tailored** to specific security risks; and
  - Implemented in a **consistent and non-discriminatory manner**.
- The practice must either implement a qualifying organizational security policy or implement a qualifying security determination

# Infeasibility

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.

**Purpose:**

that legitimate practical challenges may limit an actor's ability to comply with requests for access, exchange, or use of EHI. An actor may not have—and may be unable to obtain—the requisite technological capabilities, legal rights, or other means necessary to enable access, exchange, or use.

**Key Conditions:**

- The practice must meet one of the following conditions:
  - Uncontrollable events
  - Segmentation
  - Infeasibility under the circumstances
- The actor must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible.

# Health IT Performance

It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.

## **Purpose:**

recognizing that for health IT to perform properly and efficiently, it must be maintained. Actors should not be deterred from taking reasonable and necessary measures to make health IT temporarily unavailable for the benefit of the overall performance of health IT.

## **Key Conditions:**

- The practice must:
  - Be implemented for a **period of time no longer than necessary**;
  - Be implemented in a **consistent and non-discriminatory manner**;
  - **Meet certain requirements** if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN.
- An actor may take action against a third-party app that is negatively impacting the health IT's performance in certain instances.

# Content & Manner

It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.

## **Purpose:**

providing clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request.

## **Key Conditions:**

- **Content Condition:**
  - Before May 2, 2022, respond to a request with EHI identified by the USCDI standard.
  - After May 2, 2022, respond to a request with all EHI.
- **Manner Condition:** An actor may need to fulfill a request in an alternative manner when the actor is:
  - Technically unable to fulfill as requested
  - Cannot reach agreeable terms.

Alternative fulfillment must comply with the order of priority described in the manner condition and must satisfy the Fees Exception and Licensing Exception, as applicable.



# Fees

It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.

**Purpose:**

Enabling actors to charge fees related to the development of technologies and provision of services that enhance interoperability, while not protecting rentseeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.

**Key Conditions:**

- Meet the basis for fees condition.
- Not be specifically excluded.
- Comply with Conditions of Certification.

# Licensing

It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

## Purpose:

Allowing actors to protect the value of their innovations and charge reasonable royalties in order to earn returns on the investments they have made to develop, maintain, and update those innovations.

## Key Conditions:

- The negotiating a license conditions: An actor must begin license negotiations with the requestor **within 10 business days** from receipt of the request and negotiate a license **within 30 business days** from receipt of the request.
- The licensing conditions include scope of rights, reasonable royalty, non-discriminatory terms, collateral terms, non-disclosure agreement
- Additional conditions relating to the provision of interoperability elements.

# Enforcement

- Complaint Process
- Facts and Circumstances Analysis
- Civil Monetary Penalties
  - Provider penalties awaiting further rulemaking
  - Conduct occurring prior to such rulemaking will not be subject to CMPs

# Next Steps

- Review and revise policies/procedures
  - Assess all points of access and exchange
  - Rethink processes
  - Review fees
  - Review timeframes for responses
  - Ensure documentation is created and maintained
- Contract review/renegotiation
- Retrain staff...and start with the frontline