



Information Blocking

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Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.
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What Makes an Individual or Entity an Information Blocker?

Elements of information blocking

- “Actor” regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception

Information Blocking – Am I an “Actor”?

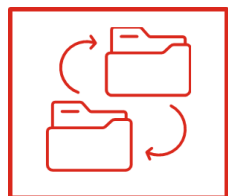
- Information blocking prohibition applies to three types of “actors”



Health Care Providers



Developers of
Certified Health IT



Health Information Networks (HINs)
& Health Information Exchanges (HIEs)

Each actor is uniquely and individually accountable for their own information blocking conduct

Knowledge Standard

Health Care Providers

“...**knows** that such practice is **unreasonable** and is likely to interfere with the access, exchange or use of electronic health information....”

Health IT Developers of Certified Health IT and HINs/HIEs

“...**knows, or should know**, that such practice is likely to interfere with the access, exchange or use of electronic health information....”

“Interfere with” or “Interference” - What is it?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- **Publication of “FHIR service base URLs” (sometimes also referred to as “FHIR endpoints”)** - A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.
- **Delays** - An actor’s practice of slowing or delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.
- **Costs for Electronic Access by Patients/Individuals** - An actor’s practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual’s EHI would be inherently suspect under an information blocking review.

Definition of Electronic Health Information (EHI)

- EHI means **electronic protected health information (ePHI)** to the extent that the ePHI is included in a **designated record set** as these terms are defined for HIPAA.
- This is applicable whether the actor is a covered entity or not.



EHI, USCDI, & the Information Blocking Definition

- From April 5, 2021 to October 6, 2022, the definition of EHI is limited to the data elements represented in the US Core Data for Interoperability (USCDI)
- Any data **represented by** data elements described within USCDI is in scope for information blocking.
- Does *not* mean that information blocking applies only to information recorded consistent with USCDI as an interoperability standard for certification

Compliance and Enforcement Timeline

- **Civil Monetary Penalties**- Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
 - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance date of the ONC final rule and will depend on when OIG issues a CMP final rule.
 - Discretion will be exercised such that conduct that occurs before the CMP rule is final will not be subject to information blocking CMPs.
- **ONC Health IT Certification Program** - On April 5, 2021, developers of certified health IT are be subject to the “information blocking” condition of certification found in 45 CFR 170.401.



Exceptions

Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI



1. **Preventing Harm Exception**



2. **Privacy Exception**



3. **Security Exception**



4. **Infeasibility Exception**

5. **Health IT Performance Exception**

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI



6. **Content and Manner Exception**



7. **Fees Exception**



8. **Licensing Exception**

Preventing Harm Exception

Overview

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.

To satisfy this exception:

The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm *and* the practice must be no broader than necessary

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The practice must satisfy at least one condition from each category: type of risk, type of harm, *and* implementation basis

+

The practice must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm



Privacy Exception

Overview

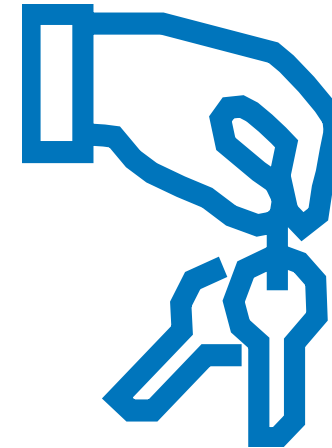
It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

To satisfy this exception,
an actor's privacy-protective practice must:

Satisfy at least one sub-exception

+

Meet all conditions applicable
to a sub-exception being relied upon





Privacy Exception : The Four Sub-exceptions

- An actor's practice of not fulfilling a request to access, exchange, or use EHI in order to protect an individual's privacy will not be considered information blocking when the practice meets all of the requirements of at least one of the sub-exceptions in this section.
 - (b) precondition not satisfied
 - (c) health IT developer of certified health IT not covered by HIPAA
 - (d) denial of an individual's request for their EHI consistent with 45 CFR 164.524(a)(1) and (2)
 - (e) respecting an individual's request not to share information

Infeasibility Exception

Overview

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.

To satisfy this exception, an actor must:

Demonstrate that the practice meets one of the conditions for uncontrollable events, segmentation, or infeasibility under the circumstances

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Provide written response, within 10 business days of receipt of the request, with the reason(s) why the request is infeasible



Content and Manner Exception

Overview

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, provided certain conditions are met.

To satisfy this exception,
an actor's practice must meet both of these conditions:

Content condition

+

Manner Condition





Content and Manner Exception

Content Condition

- **From April 5, 2021 to October 6, 2022**, an actor must respond to a request to access, exchange, or use EHI with, *at a minimum*, the requested EHI that is identified by the data elements **represented in** the USCDI standard.
- **On and after October 6, 2022**, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.

Points of Interest:

- ! **Can** be met if the actor does not have all the requested EHI.
- ! Does **not** require EHI be held in or shared using specific technology or particular technical standards.
- ! **Can** be met where some EHI is withheld due to laws or is permissible to be withheld, such as under the Preventing Harm or Privacy exceptions.





Content and Manner Exception

Manner Condition – Any Manner Requested

- An actor must fulfill a request **in any manner** requested *unless* the actor is:
 1. Technically unable to fulfill the request in a manner requested; **or**
 2. Cannot reach agreeable terms with the requestor to fulfill the request.
- If an actor fulfills a request in **any manner requested**, the actor's practice is **not** subject to the Fees or Licensing Exceptions.





Content and Manner Exception

Manner Condition – Alternative Manner

- If an actor responds in an **alternative manner**, the actor must fulfill the request **without unnecessary delay** in the **following order of priority**, only proceeding to the next consecutive paragraph if **technically unable** to fulfill the request in that manner:
 1. Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.
 2. Using content and transport standards specified by the requestor and published by:
 - Federal Government; or
 - Standards developing organization accredited by the American National Standards Institute.
 3. Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.



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