Information Blocking: What Do I Need to Know and Do?

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21st Century Cures Act, Section 4004

- Defines “information blocking”
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking
21st Century Cures Act, Section 4004

- Identifies the HHS Office of Inspector General (OIG) as the HHS office to investigate claims of information blocking and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR)
- Prescribes penalties for information blocking
- Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints
What is Information Blocking?

Practices that restrict authorized access, exchange, or use under applicable state or federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies (health IT);
What is Information Blocking?

Information blocking means a practice that—

- Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information (EHI); and

- If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

- Until date specified in 45 CFR 171.103(b), EHI for purposes of § 171.103(a) is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.
USCDI v1 (v2 is in Draft)

**Allergies and Intolerances**
- Substance (Medication)
- Substance (Drug Class)
- Reaction

**Clinical Notes**
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

**Patient Demographics**
- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

**Goals**

**Health Concerns**

**Immunizations**

**Laboratory**
- Tests
- Values/Results

**Procedures**

**Provenance**
- Author Time Stamp
- Author Organization

**Smoking Status**

**Unique Device Identifier(s) for a Patient’s Implantable Device(s)**

**Vital Signs**
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 years old)
- Weight-for-length Percentile (Birth - 36 months)
- Occipital-frontal Head Circumference Percentile (Birth - 36 months)

**For more info:**
HealthIT.gov/USCD

HIPAAAtrek
Guiding Your HIPAA Compliance
What is EHI?

EHI means **electronic protected health information (ePHI)** to the extent that the ePHI would be 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.
Are You 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, prevent, or materially discourage access, exchange, or use of EHI
• Requisite knowledge by the actor
• Not required by law
• Not covered by an exception
What do you think?

If a patient calls and requests access to their lab results, are you permitted to withhold the information until the provider is able to review them?
Patient Access – Free of Charge “Open Notes”

Immediate Electronic Access (cannot be held for review)

- Consultation notes
- Discharge summary notes
- History and physical
- Imaging narratives
- Laboratory report narratives
- Pathology report narratives
- Procedure notes
- Progress notes
Interference or Interfere with

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

- Publication of FHIR URLs (endpoints) cannot be withheld
- Cost for electronic access by a patient or individual
- Educate patients about 3rd part apps
  - Must be factual
  - Must not be discriminatory
  - Focus on privacy/security risks
- Delays of access
  - Lab results example
Is it Information Blocking?

Use what you just learned...

Your organization regularly uploads information to the patient portal; however, you selectively withhold pushes to the portal such as diagnostic testing (labs and imaging reports) for review.

Keep in mind: the Rule does not require you to proactively push lab results and other data to a patient portal.
What do you think?

If another provider calls to request records on a patient, are you permitted to withhold the records until you have authorization from the patient?
No Longer “Just” Permissible – Now REQUIRED

- Disclosures for treatment purposes
- Patient authorization NOT required to disclose
- Must be facilitated without delay

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Exceptions
Exceptions

The exceptions to Information Blocking are activities that will NOT be considered information blocking.

Two categories:
1) Not fulfilling access, exchange, or use ePHI
2) Procedures for fulfilling access, exchange, or use ePHI
Preventing Harm Exception

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

Must hold a reasonable belief that withholding information will substantially reduce a risk of harm

Restriction of data must not be broader than necessary

Must satisfy at least one condition from each of the following categories:

- Type of risk
- Type of harm
- Implementation basis

Must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm
A patient has called and requested their genetic test results for a genetic disease for which there is no effective cure or treatment. Are you permitted to delay disclosure of these test results until a provider is able to review the results with the patient?

Keep in mind:

- The exception does not have consideration for emotional harm prevention.
- The exception requires a reasonable belief that withholding the information reduces the harm to life or physical safety.
Is it Information Blocking?

Use what you just learned...

A patient’s spouse calls requesting records. The patient has visited your facility several times with injuries you suspect were caused by domestic violence. Are you permitted to withhold information from a personal representative you believe is an abuser?

Keep in mind:

• The exception does not have consideration for emotional harm prevention.
• The exception requires a reasonable belief that withholding the information reduces the harm to life or physical safety.
**Privacy Exception**

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

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**Precondition not satisfied:** If a clinic or hospital is required by a state or federal law to satisfy a precondition (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI, the actor may choose not to provide access, exchange, or use of such EHI if the precondition has not been satisfied under certain circumstances.

**Denial of an individual’s request for their EHI consistent with 45 CFR 164.524(a) (1) and (2):** A hospital or clinic may deny an individual’s request for access to his or her EHI in the circumstances provided under 45 CFR 164.524(a)(1) and (2) of the HIPAA Privacy Rule.

**Respecting an individual’s request not to share information:** A hospital or clinic 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.
You are a hospital that has a Part 2 Program that has treated the patient under the Part 2 Program AND as a Covered Entity. You receive a request from another provider for all records on a patient. Are you permitted to withhold ONLY the Part 2 data until you are able to obtain patient consent?

Keep in mind:

• CURES only applies to PERMISSIBLE disclosures
• The exception only applies until the precondition is satisfied
<table>
<thead>
<tr>
<th>Security Exception</th>
<th>Must be directly related to safeguarding the confidentiality, integrity, and availability of EHI</th>
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<tbody>
<tr>
<td></td>
<td>Must be tailored to specific security risks; AND</td>
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<tr>
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<td>Must be implemented in a consistent and non-discriminatory manner</td>
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<tr>
<td></td>
<td>Must implement a security policy or implement a qualifying security determination</td>
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Security Exception

It will not be information blocking for a clinic or hospital to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met. This exception is meant to cover all legitimate security practices; but does not prescribe a maximum level of security or dictate a one-size-fits-all approach.
Is it Information Blocking?

Use what you just learned...

Are you permitted to deny a request to push EHI to an API if you question the security of the API?

Keep in mind:
• Must be tailored to a SPECIFIC risk
• This exception requires a policy
Infeasibility Exception

It will not be information blocking if a clinic or hospital does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met. This exception recognizes that legitimate practical challenges may limit the ability to comply with requests for access, exchange, or use of EHI. The clinic or hospital 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.

Uncontrollable events: The clinic or hospital cannot fulfill the request for access, exchange, or use of electronic health information due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.

Segmentation: The clinic or hospital cannot fulfill the request for access, exchange, or use of EHI because they cannot unambiguously segment the requested EHI.

Infeasibility under the circumstances: The clinic or hospital demonstrates through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of certain factors that led to its determination that complying with the request would be infeasible under the circumstances.

Must provide written notice to the requestor within 10 days of receipt of the request with the reason why the request is infeasible.
Is it Information Blocking?
Use what you just learned...

If a competing physician, who is not credentialed with your hospital, requests EHI be pushed to its EMR in a manner used with credentialed physicians, are you permitted to withhold or delay the request?

Keep in mind:
- The Rule requires all USCDI data points to be disclosed.
- The exception requires that you implement it in a non-discriminatory manner.
Health IT Performance Exception

It will not be information blocking for a clinic or hospital 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. This exception recognizes that for health IT to perform properly and efficiently, it must be maintained, and in some instances improved, which may require that health IT be taken offline temporarily. Clinics and hospitals should not be deterred from taking 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 health IT.

The practice must:

• Be implemented for a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable or the health IT’s performance degraded;
• Be implemented in a consistent and non-discriminatory manner; and
• Meet certain requirements if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN.

A clinic or hospital may take action against a third-party app that is negatively impacting the health IT's performance, provided that the practice is:

• For a period of time no longer than necessary to resolve any negative impacts;
• Implemented in a consistent and non-discriminatory manner; and
• Consistent with existing service level agreements, where applicable.

If the unavailability is in response to a risk of harm or security risk, the clinic or hospital must only comply with the Preventing Harm or Security Exception, as applicable.
Is it Information Blocking?
Use what you just learned...

If your EMR is undergoing maintenance and you receive a request for EHI while the EMR is down, are you permitted to delay the request?

Keep in mind:
- The exception is limited in time to only the necessary timeframe to improve IT performance.
- If the Health IT performance is suffering due to a security breach or prevention of harm, you will need to consider an alternative exception.
Content and Manner Exception

It will not be information blocking for a clinic or hospital 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. This exception provides clarity and flexibility to clinics or hospitals concerning the required content (i.e., scope of EHI) of a response to a request to access, exchange, or use EHI in order to satisfy the exception.

**Content Condition:**
Establishes the content a clinic or hospital must provide in response to a request to access, exchange, or use EHI in order to satisfy the exception.

- Up to 24 months after the publication date of the Cures Act final rule, a clinic or hospital must respond to a request to access, exchange, or use EHI with, at a minimum, the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) standard.

- On and after 24 months after the publication date of the Cures Act final rule, a clinic or hospital must respond to a request to access, exchange, or use EHI with EHI as defined in §171.102.

**Manner Condition:**
Establishes the manner in which a clinic or hospital must fulfill a request to access, exchange, or use EHI in order to satisfy this exception.

- A clinic or hospital may need to fulfill a request in an alternative manner when the clinic or hospital is:
  - Technically unable to fulfill the request in any manner requested; or
  - Cannot reach agreeable terms with the requestor to fulfill the request.

- If a clinic or hospital fulfills a request in an alternative manner, such fulfillment must comply with the order of priority described in the manner condition and must satisfy the Fees Exception and Licensing Exception, as applicable.
Is it Information Blocking?
Use what you just learned...

A patient requests records that you are permitted to share; however, you do not have the technical capability to share the information in the manner the patient requests the information. Are you permitted to delay the request?

Keep in mind:

• The exception has deadlines for being able to respond to content (or the what) of a request.
• The exception requires you to consider alternative manners (or the how) to fulfill the request.
Fees Exception

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. This exception enables actors to charge fees related to the development of technologies and provision of services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.

- Meet the basis for fees condition.
  - For instance, the fees an actor charges must:
    - Be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests.
    - Be reasonably related to the actor’s costs of providing the type of access, exchange, or use of EHI.
    - Not be based on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor.
Is it Information Blocking?
Use what you just learned...

Your organization decides to develop a proprietary software to help facilitate access to records. Are you permitted to charge a fee to patients for them to utilize this amazing new piece of technology you created?

Keep in mind:
- HIPAA prohibits charging patients more than cost-based fees for accessing their records.
- The Rule requires patients are granted free and immediate access (Open Notes).
Licensing Exception

This exception allows 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. Meet the basis for fees condition.

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:
- Scope of Rights
- Reasonable Royalty
- Non-discriminatory terms
- Collateral terms
- Non-disclosure agreement

Additional conditions relating to the provision of interoperability elements.
A patient requests that you receive the information through a 3rd party app’s API. The 3rd party app developer contacts you to about the technical details to connect to the app. Are you permitted to ignore the request?

Keep in mind:

- If the API has FHIR capability
- Consider the timelines for this exception
- Consider other exceptions discussed
Compliance and Enforcement
Consequences of Information Blocking

- **Cures Act prescribes penalties for information blocking**
  - Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to $1 million per violation
  - Health care providers → Appropriate disincentives
  - CMS will publish a list of providers who cannot attest they are in compliance with Prevention of Information Blocking (MIPS has 3 attestation statements)

- **Certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
  - Information blocking Condition of Certification (§ 170.401)
  - Public listing of certification bans and terminations
Compliance and Enforcement Timeline

ONC Health IT Certification Program - On April 5, 2021, developers of certified health IT will be subject to the “information blocking” condition of certification found in 45 CFR 170.401.

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.
Dates to Know

Information Blocking

4/5/2021
Applicability Date for Information Blocking Provisions

4/5/2021 through 10/5/2022
EHI definition is limited to the EHI identified by the data elements represented in the USCDI

On and after 10/6/2022
EHI definition is no longer limited to the EHI identified by the data elements represented in the USCDI

Source: ONC
Questions?

CRHCP Code:

479WK

Please note: This code is only for those that are currently certified. If you are interested in certification, please contact academy@narhc.org.
Compliance is Quality Patient Care!

Contact us to learn more!

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