Information Sharing under the ONC Cures Act
Final Rule: Transition from USCDI to the Full Scope of EHI Definition

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Disclaimer

Please Note

• The materials contained in this presentation are based on the provisions contained in the 21st Century Cures Act and 45 C.F.R. Part 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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Information Blocking in the 21st Century Cures Act

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
- 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
Information Sharing Under Section 4004 of the 21st Century Cures Act

Patients
✓ Improves patient engagement
✓ Easier access to health information
✓ Privacy preferences are respected

Clinicians & Other Health Care Providers
✓ Improves access to information to deliver the best care
✓ Improves care coordination
✓ Improves choice of software

Health IT Developers
✓ Encourages innovation to lessen burden
✓ Enhances the value of technology to clinicians and other health care providers
**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

**Abbreviations:**

- **EHI** = Electronic Health Information
- **USCDI** = United States Core Data for Interoperability
Information Blocking Definition

45 CFR 171.103

(a) Information blocking means a practice that—

(1) 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

(2) If conducted by a health information technology developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of EHI; or

(3) 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.

(b) For the period before October 6, 2022, electronic health information for the purposes of paragraph (a) of this section is limited to the electronic health information identified by the data elements represented in the USCDI standard adopted in § 170.213.
Information Blocking – Am I an “Actor”?

• Information blocking regulation applies to three types of “actors.”

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

Health Care Providers

Health IT Developers of Certified Health IT

Health Information Networks (HINs) & Health Information Exchanges (HIEs)
Proposed Electronic Health Information Definition

*Electronic Health Information (EHI)* means—

(1) Electronic protected health information; and

(2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
Final Electronic Health Information Definition

• Electronic Health Information (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.

• Except for psychotherapy notes (45 CFR 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

• This is applicable whether or not the information is held by or for a HIPAA covered entity.

• Does **not** limit EHI to what is recorded or exchanged consistent with any specific interoperability standard.
Understanding the Scope of EHI for Purposes of the Information Blocking Definition

Infographic does not depict the actual scope of each category, or the relative proportion of the various categories within any given record set.
EHI is Not Limited by when the Information was Generated

• The definition of electronic health information (EHI) is not limited by when the information was generated. Before October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, the requested EHI that they have and that can be identified by the data elements represented in the United States Core Data for Interoperability (USCDI), regardless of when the information was generated.

Exceptions: Reasonable and Necessary Activities

Promote confidence in health IT infrastructure
- Privacy and security
- Patient safety

Promote competition and innovation
- Usability and modernization of technology
- Greater value, more choices, reduced burden

Promote standardization and interoperability
- Greater accessibility, including for research
- Better quality and equitable health outcomes

Exceptions Policy
1. Identify certain reasonable and necessary activities that do not constitute information blocking
2. Address practices of significant risk for actors not engaging in them due to uncertainty about the information blocking regulations
3. Through appropriate conditions, limit to protect and not extend beyond, reasonable and necessary activities
Information Blocking Exceptions

• **Information Sharing**: the norm is to avoid actions or omissions ("practices") that are likely to interfere with information sharing.

• **Exceptions**: the exceptions offer assurance that reasonable and necessary "practices" covered by an exception will not be considered information blocking.

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<th>Applicable to delaying, restricting, or denying access, exchange, or use</th>
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<th>Applicable to processes or procedures for fulfilling access, exchange, or use of EHI</th>
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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.

Content and Manner Exception

- Actor must meet BOTH conditions:
  1. Content condition
     • Before October 6, 2022, EHI identified by the data elements represented in USCDI standard.
     • On and after October 6, 2022, EHI without the limitation.
  2. Manner condition
     • Any manner unless: (1) technically unable to fulfill in the manner requested; or (2) cannot reach agreeable terms with the requestor.
Infeasibility Exception

One of Three Conditions - 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.

- **Uncontrollable Events**: Must be due to events beyond the actor’s control.
- **Segmentation**: Cannot unambiguously segment the requested EHI from other EHI.

Infeasibility Under the Circumstances – Factor Test

“...[T]hrough a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors…:”

- Type of EHI and the purposes for which it may be needed;
- Cost to the actor of complying with the request in the manner requested;
- Financial and technical resources available to the actor;
- Whether the practice is non-discriminatory and “same access comparison;”
- Whether the actor owns or has control over the tech, platform, or HIN/HIE; and
- Why the Content and Manner Exception didn’t “work”
Where Can You Find More Information?

Education & Outreach Resources

- Frequently Asked Questions (FAQs)
- Factsheets
- Technical Assistance and Guides
- Webinars and Other Presentations
- Health IT Buzz Blog
- Health IT Feedback and Inquiry Portal
- Information Blocking Portal Process
- [Understanding Electronic Health Information (EHI) Fact Sheet](https://www.healthit.gov/report-info-blocking)
- ONC Speaker Request Form [https://www.healthit.gov/speaker-request-form](https://www.healthit.gov/speaker-request-form)
What if You Are Experiencing Information Blocking?

• The Cures Act directs the National Coordinator to implement a standardized process for the public to submit reports on claims of information blocking.

• A report of potential information blocking can be submitted through the Report Information Blocking Portal: https://healthit.gov/report-info-blocking
Contact ONC

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

Twitter: @onc_healthIT

LinkedIn: Search “Office of the National Coordinator for Health Information Technology”

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