

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

Elise Sweeney Anthony, Executive Director, Office of Policy, ONC

Michael Lipinski, Director, Regulatory and Policy Affairs Division, Office of Policy, ONC

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.
- This communication is produced and disseminated at U.S. taxpayer expense.

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

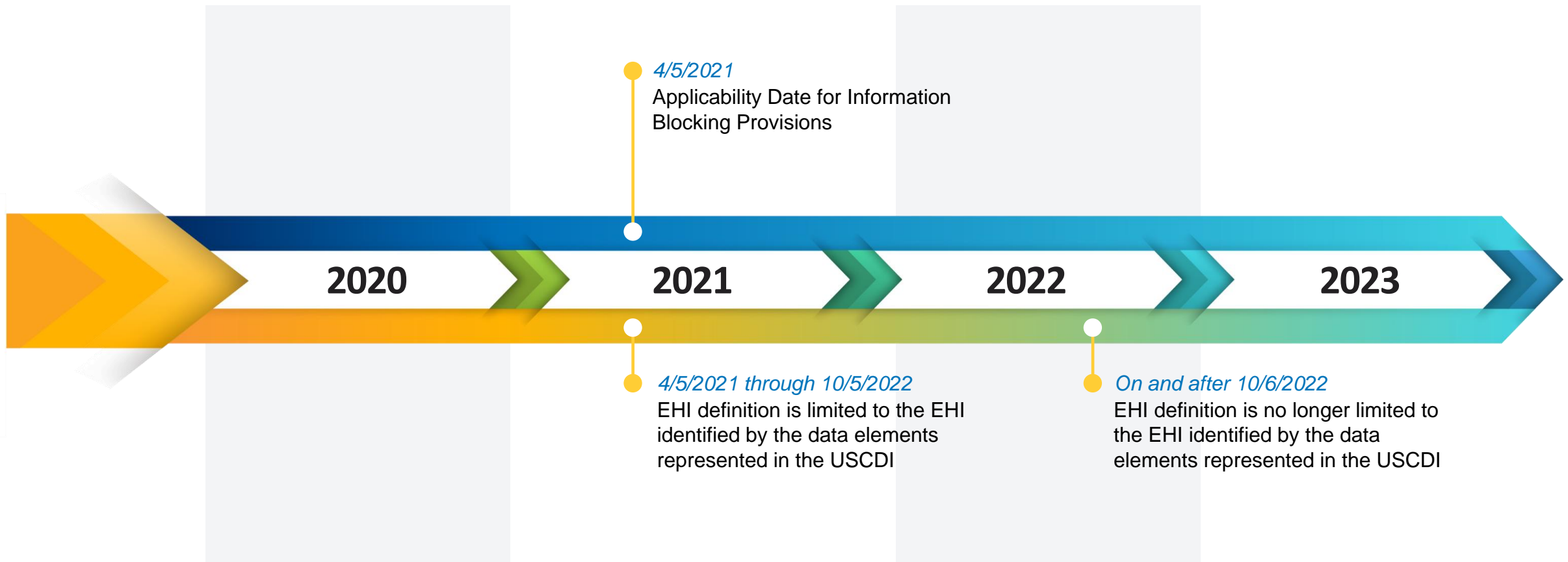
- ✓ Improves access to information to deliver the best care
- ✓ Improves care coordination
- ✓ Improves choice of software

Health IT Developers

- ✓ Encourages innovation to lessen burden
- ✓ Enhances the value of technology to clinicians and other health care providers



Information Blocking



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](#).

VERSION 1

Elements of Information Blocking

- Not “required by law”
- Not covered by an exception
- Likely to “interfere with” access, exchange, or use
- Electronic health information (EHI)
- By a health IT developer of certified health IT, HIE/HIN, or health care provider (an information blocking “actor”)
- Actor has requisite knowledge

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

Information Blocking – Am I an “Actor”?

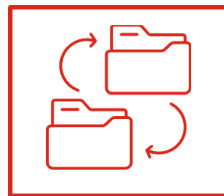
- Information blocking regulation applies to three types of “actors.”
- Each actor is uniquely and individually accountable for their own information-blocking conduct.



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

Health IT Buzz
The Latest on Health Information Technology from ONC

Search

Health IT Buzz > Information Blocking > Say Hi to EHI

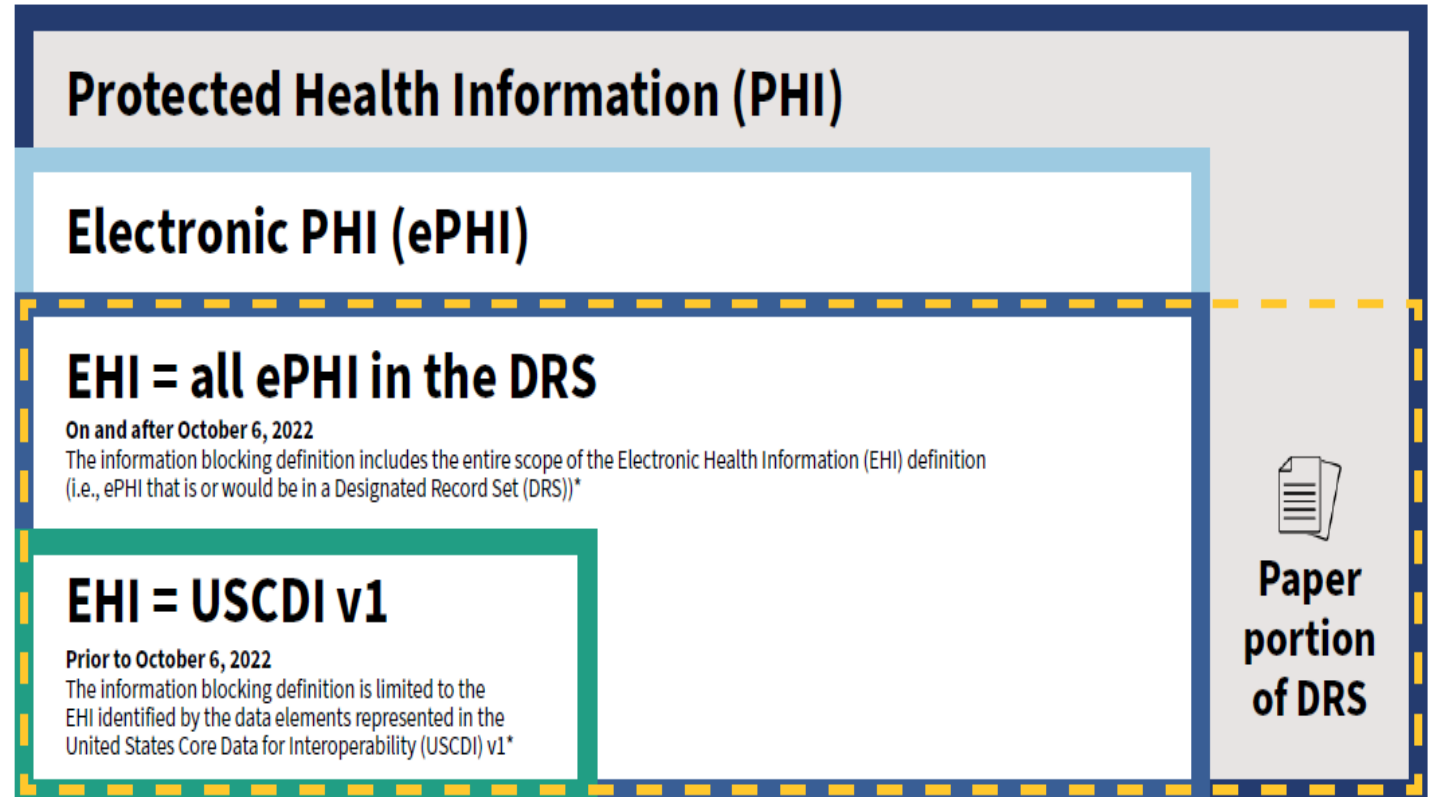
Information Blocking

Say Hi to EHI

Kathryn Marchesini and Michael Lipinski | DECEMBER 20, 2021

Tweet Share LinkedIn Email

ONC's information blocking regulations apply to interferences with the access, exchange, or use of electronic health information (EHI) (45 CFR Part 171) and define certain exceptions to the definition of information blocking. Thus, it's important that those subject to the information blocking regulations – health care providers, developers of certified health IT, and health information networks/exchanges (cumulatively, “actors”) – understand what health information the regulations cover. So, what is EHI anyway?



— Designated Record Set (DRS) Scope

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.
- See: IB.FAQ20.1.2020NOV (<https://www.healthit.gov/curesrule/faq/electronic-health-information-ehi-covered-information-blocking-regulations-limited-when>)

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**.

Applicable to delaying, restricting, or denying access, exchange, or use

1. **Infeasibility Exception**
2. Preventing Harm Exception
3. Privacy Exception
4. Security Exception
5. Health IT Performance Exception

Applicable to processes or procedures for fulfilling access, exchange, or use of EHI

6. **Content and Manner Exception**
7. Fees Exception
8. Licensing Exception

Content and Manner Exception

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.
- AND**
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”

Infeasibility Exception

- **Actor must demonstrate that the practice meets 1 of 3 conditions for:**
 1. uncontrollable events
 2. segmentation, OR
 3. infeasibility under the circumstances
- **Must provide written response within 10 business days of request with the reason(s) why it is infeasible**



Where Can You Find More Information?

Education & Outreach Resources

- www.HealthIT.gov/CuresRule
- Frequently Asked Questions (FAQs)
- Factsheets
- Technical Assistance and Guides
- Webinars and Other Presentations
- Health IT Buzz Blog
- Report Information Blocking Portal: healthit.gov/report-info-blocking
- Health IT Feedback and Inquiry Portal
- [Information Blocking Portal Process](#)
- [Understanding Electronic Health Information \(EHI\) Fact Sheet](#)
- ONC 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>



**Report information
blocking**



The Office of the National Coordinator for
Health Information Technology

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”



**Subscribe to our weekly eblast
at [healthit.gov](https://www.healthit.gov) for the latest updates!**