

Electronic Health Information Sharing

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General Disclaimers

- **The information in this presentation is based on the regulations in 45 CFR Part 171.**
- While every effort has been made to ensure accuracy, this presentation is not a legal document. Please note that other federal, state and local laws may apply.
- Examples are merely illustrative and may be simplified for ease of discussion.
- Any practice (act or omission) that implicates the information blocking regulations may come under investigation by HHS.
- 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 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](#).

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 Definition – 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

Information Blocking – Am I an “Actor”?

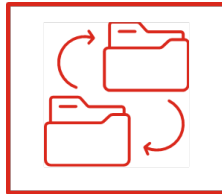
- Information blocking regulation applies to three types of “actors.”
- Each actor is uniquely and individually accountable for their own information-blocking conduct.



Health Care Providers



Health IT Developers of Certified Health IT



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

Health Care Provider Definition

Public Health Service Act (42 U.S.C. 300jj)

The term “health care provider” includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title, a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

https://www.healthit.gov/sites/default/files/page2/2020-08/Health_Care_Provider_Definitions_v3.pdf

Health Information Exchange/ Health Information Network (HIE/HIN)

- ***Health information network or health information exchange*** means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:
 - (1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and
 - (2) That is for a treatment, payment, or health care operations purpose, as such terms are defined in [45 CFR 164.501](#) regardless of whether such individuals or entities are subject to the requirements of [45 CFR parts 160](#) and 164. ([45 CFR 171.102](#))
- Focuses on three activities: Treatment, payment, and health care operations, as each are defined in the HIPAA Rules ([45 CFR 164.501](#))
- Functional definition, not limited to individuals or entities that are covered entities or business associates (as defined by HIPAA)

What is Electronic Health Information?

- 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.
- **EHI includes data that is not recorded or exchanged consistent with any specific interoperability standard.**



Understanding the Scope of EHI for Purposes of the Information Blocking Definition



HealthITBuzz
The Latest on Health Information Technology from ONC

Search

Health IT Buzz > Information Blocking > Say Hi to EHI

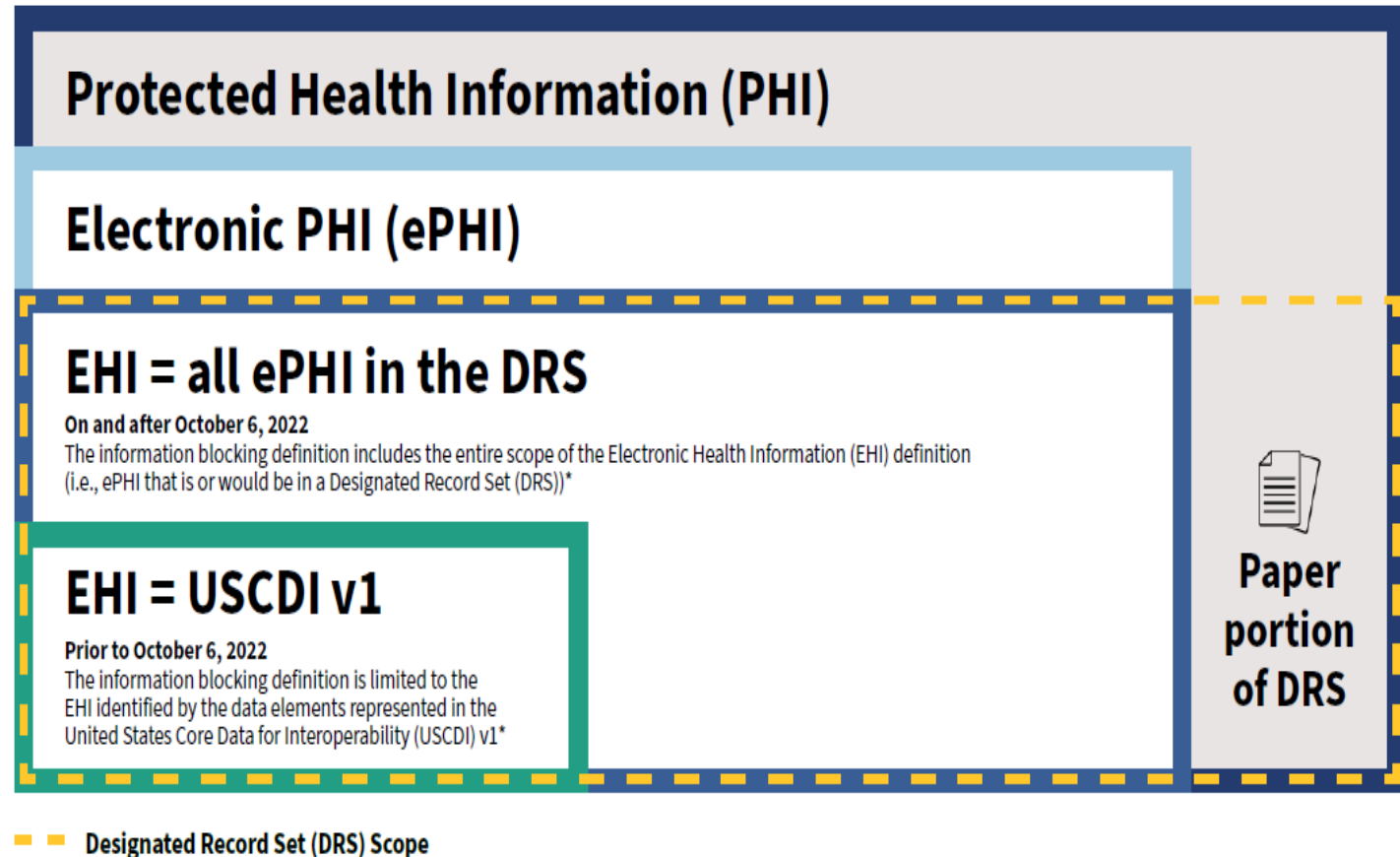
Information Blocking

Say Hi to EHI

Kathryn Marchesini and Michael Lipinski | DECEMBER 20, 2021

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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?



Infographic does not depict the actual scope of each category, or the relative proportion of the various categories within any given record set.

Required by Law

What does it mean?

- Refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.
- Distinguishes between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law.”

Clarification from the Final Rule

Federal and state law includes:

- Statutes, regulations, court orders, and binding administrative decisions or settlements, such as (at the Federal level) those from the FTC or the Equal Employment Opportunity Commission (EEOC)
- Tribal laws, as applicable

What happens when a claim is submitted to the Information Blocking Portal?

The Office of the National Coordinator for
Health Information Technology

*This guide is for informational purposes only.
The official requirements are contained in the relevant statutes and regulations.*

✉ **Points at which ONC communicates with submitter**

ONC Scope

The Office of the National Coordinator for
Health Information Technology

ONC acknowledges receipt of the claim and shares it with OIG. ✉

Is it a claim against a Healthcare Provider?

Yes →

No ↓

Is it a claim against a Health Information Network/Health Information Exchange?

Yes →

No ↓

Is it a claim against an Offeror of Certified Health IT?

Yes →

No ↓

Is it a claim against a Health IT Developer of Certified Health IT?

Yes →

Yes →

ONC may investigate and may take action under the ONC Health IT Certification Program* ✉

***For example, ONC may issue a Notice of Non-conformity to the developer because the developer's actions did not conform to the Certification Program requirement in 45 CFR § 170.401. A developer may be required to submit a Corrective Action Plan and could also face suspension or termination of the certification.*

Not an information blocking claim.
No information blocking authority for ONC or OIG. ONC informs the submitter. ✉

OIG Scope



OIG Authority: OIG may investigate, and the HCP may be subject to appropriate disincentives.*

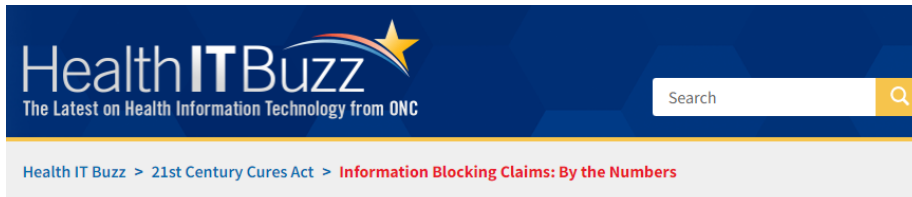
OIG Authority: OIG may investigate and may issue civil monetary penalties.

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OIG Authority: OIG may investigate and may issue civil monetary penalties.

**Appropriate disincentives will be established by HHS in a future rulemaking.*

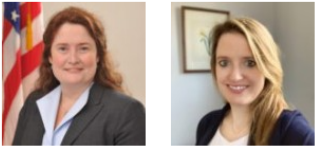
IB Claims: By the Numbers



21st Century Cures Act, Information Blocking

Information Blocking Claims: By the Numbers

Rachel Nelson and Cassie Weaver | FEBRUARY 28, 2022



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The 21st Century Cures Act (Cures Act), signed into law by President Obama in 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking. The information blocking claims reporting process welcomes claims of possible information blocking from **anyone** who believes they may have experienced or observed information blocking. Any information received by ONC in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information (claimant) is protected from disclosure under the Cures Act. The Cures Act authorizes the HHS Office of Inspector General (OIG) to investigate any claim of information blocking.

Today, we posted a [Quick Stat](#) visualization of data on the information blocking claims we have received through the [Report Information Blocking Portal](#) since April 5, 2021—the applicability date of the [information blocking regulations](#). Moving forward, we generally plan to update these resources on a monthly basis and provide our data in two formats—a [web page](#) showing cumulative numbers to date and a [downloadable file \[XLSX – 92 KB\]](#) that shows what the cumulative counts were each month dating

<https://www.healthit.gov/buzz-blog/21st-century-cures-act/information-blocking-claims-by-the-numbers>



Source

Submissions received through the Report Information Blocking Portal.

Citation

Office of the National Coordinator for Health Information Technology. 'Information Blocking Claims: By the Numbers,' Health IT Quick-Stat #59 <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>. May 2022.

Overview Notes

The 21st Century Cures Act (Cures Act), signed into law by President Obama in December 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking¹. This Quick Stats page displays data on claims or suggestions of possible information blocking¹ ONC has received through the Report Information Blocking Portal since April 5, 2021 – the applicability date of the information blocking regulations.

To best understand and use the information provided, it will be important to keep the following in mind:

- Information provided about the perspectives of those submitting claims and the types of potential actors alleged to be information blocking is based solely on an ONC analyst's inference from the facts and allegations as presented by the claimant.
- Any claim ONC receives is simply an allegation or suggestion that information blocking has occurred. Logging a portal submission as a claim does **not** imply that an investigation has occurred or been started, or that any determination has been made as to whether information blocking has occurred.

¹ Where a claim alleges or suggests that conduct implicating the information blocking definition in 45 CFR 171.103 could

<https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>

2015 Edition “EHI Export” Criterion and IB

Scope

Uses the same EHI definition as the information blocking regulations, but the scope of data that needs to be exported is that which can be stored at the time of certification by the product.

Information Blocking (IB)

If the EHI export would be performed using health IT certified under the ONC Health IT Certification Program (45 CFR Part 170) to the “EHI Export” certification criterion (45 CFR 170.315(b)(10)), a fee that is charged to perform such export for purposes of switching health IT or to provide patients their electronic health information (45 CFR 171.302(b)(3)) would not qualify for the “Fees Exception.”

General Requirements

A certified Health IT Module must include export capabilities for:

- a) a single patient EHI export to support patient access and
- b) patient population EHI export to support transitions between health IT systems

The export file(s) created must:

- a) be electronic and in a computable format, and
- b) the publicly accessible hyperlink of the export's format must be included with the exported file(s).




Note: Health IT developers have the flexibility to determine their products' standard format for the purpose of representing the exported EHI.

Update and provide by: December 31, 2023

What's New and What's Next?

- **Advisory Opinions Congressional Request**
- **Upcoming Regulatory Action**
- **Frequently Asked Questions (FAQs), Infographics, and Other Educational Resources**
- **Stakeholder Outreach**

President's FY23 Budget for ONC




The Latest on Health Information Technology from ONC

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[Information Blocking](#)

Information Blocking and the President's FY23 Budget for ONC

Steven Posnack | MAY 24, 2022



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While the federal government's budget planning processes may have a certain mystique to them, some interesting tidbits are always in federal agency budgets if you know where to look. Fear not, because this blog post highlights a new legislative proposal associated with information blocking that's been put forward by the Biden-Harris Administration for HHS. Specifically, the Administration has requested that Congress provide HHS with the authority to issue binding "advisory opinions" for the information blocking regulations as part of our implementation of the 21st Century Cures Act (Cures Act).

The President's fiscal year (FY) budget proposals are published every spring for the forthcoming fiscal year. This process is a way for the Executive Branch to inform the Legislative Branch of its priorities and needs, including funding and authorities. In some cases, when the Administration determines that additional or new authority is needed, the President's budget also includes these requests.

Office of the National Coordinator for Health IT

FY 2023 President's Budget: Justification of Estimates to the Appropriations Committees

Proposed Law

1. Advisory Opinions for Information Blocking

Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.

ONC NPRM - Spring 2022 Unified Agenda



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View Rule

[View EO 12866 Meetings](#)
[Printer-Friendly Version](#)
[Download RIN Data in XML](#)
HHS/ONC
RIN: 0955-AA03

Publication ID: Spring 2022

Title: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.

Agency: Department of Health and Human Services(HHS)

Priority: Other Significant

RIN Status: Previously published in the Unified Agenda

Agenda Stage of Rulemaking: Proposed Rule Stage

Major: Undetermined

Unfunded Mandates: No

CFR Citation: [45 CFR 170](#) [45 CFR 171](#) [45 CFR 172](#)

Legal Authority: [42 U.S.C. 300jj-11](#) [42 U.S.C. 300jj-14](#) [42 U.S.C. 300jj-19a](#) [42 U.S.C. 300jj-52](#) [5 U.S.C. 552](#) [Pub. L. 114-255](#) [Pub. L. 116-260](#)

Legal Deadline:

Action	Source	Description	Date
Final	Statutory	Conditions of certification and maintenance of certification	12/13/2017
Final	Statutory	Publish a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement.	07/24/2019

Timetable:

Action	Date	FR Cite
NPRM	10/00/2022	
NPRM Comment Period End	12/00/2022	

ONC NPRM – OMB Acceptance for Review



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Pending EO 12866 Regulatory Review

RIN: 0955-AA03 View EO 12866 Meetings	Received Date: 09/01/2022
Title: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing	
Agency/Subagency: HHS / ONC	
Legal Deadline: Statutory	
International Impacts: No	
Pandemic Response: No	
Stage: Proposed Rule	
Economically Significant: Yes	
Affordable Care Act [Pub. L. 111-148 & 111-152]: No	
Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No	

Examples of EHI-Related FAQs at HealthIT.gov

Do the information blocking regulations (45 CFR Part 171) require actors to make patients aware of newly available electronic health information (EHI)? (IB.FAQ44.1.2022FEB)

There is no specific regulatory provision under the information blocking regulations that expressly requires actors to make individuals aware of newly available [EHI](#), whether from a recent clinical encounter or newly available historical EHI not previously accessible to a patient. In most circumstances, [practices](#) to notify patients (e.g., by text alert or email) about newly available EHI or stopping such notifications would likely *not* be considered information blocking.

Please see the following FAQ for more information on how practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking: [Q: How would any claim or report of information blocking be evaluated? \(IB.FAQ46.1.2022FEB\)](#)

Can an actor grant a patient's request to delay the release of a patient's test result(s) (e.g., laboratory or image result(s)) to the patient without implicating the information blocking regulations? (IB.FAQ45.1.2022FEB)

It would likely *not* be an interference when an actor follows an individual patient's, or patient's representative's, request to delay release of the patient's electronic health information (EHI) to the patient or to the patient's representative.

In the preamble to the 21st Century Cures Act final rule, we recognized that "some delays may be legitimate" ([85 FR 25813](#)) and not an interference (as defined in [45 CFR 171.102](#)). However, the unique facts and circumstances of each situation would need to be evaluated. Generally, a delay should be for no longer than necessary to fulfill each patient's request (see [85 FR 25813](#); see also [85 FR 25878](#) and [45 CFR 171.301\(b\)\(2\)\(i\)](#)).

<https://www.healthit.gov/curesrule/faq/do-information-blocking-regulations-45-cfr-part-171-require-actors-make-patients-aware-newly>

<https://www.healthit.gov/curesrule/faq/can-actor-grant-patients-request-delay-release-patients-test-results-eg-laboratory-or-image>

Upcoming Information Sharing Events



Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

[TOPICS](#)[BLOG](#)[NEWS](#)[DATA](#)[ABOUT ONC](#)

[Home](#) > [Upcoming Events](#)

Ask Us About Information Sharing

SEP 22, 2:00-3:00PM ET | OCT 6, 2:00-3:00PM ET | OCT 27, 2:00-3:00PM ET

[Register For September 22, 2:00 - 3:00 Pm](#) 

[Register For October 6, 2:00 - 3:00 Pm](#) 

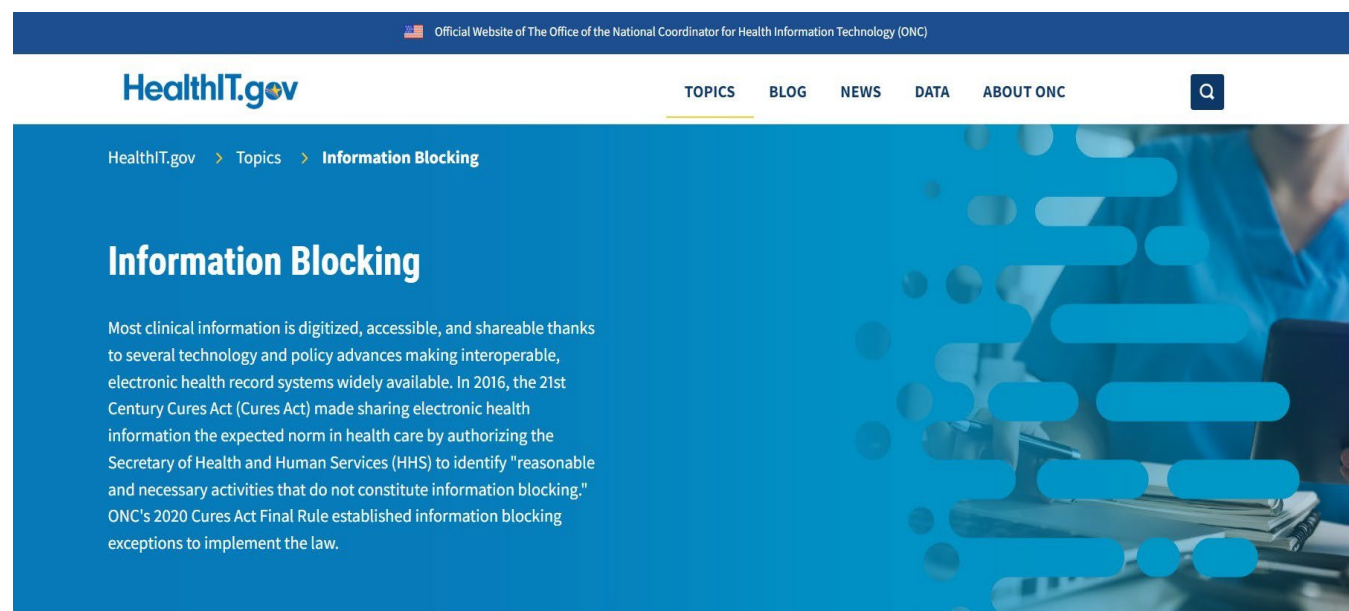
[Register For October 27, 2:00 - 3:00 Pm](#) 

Got questions about information sharing under ONC's information blocking regulations? Join ONC's experts for our virtual office hours on September 22, October 6, and October 27 from 2:00 – 3:00 pm ET to ask us about the information blocking regulations.

Where Can You Find More Information?

Education & Outreach Resources

- <https://www.healthit.gov/topic/information-blocking>
- 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](https://www.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>





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Health IT Feedback Form:

[https://www.healthit.gov/form/
healthit-feedback-form](https://www.healthit.gov/form/healthit-feedback-form)



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