Office of the National Coordinator for Health Information Technology

Information Blocking

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Disclaimers

- The materials contained in this presentation are based on the provisions contained in 45 CFR Parts 170 and 171 and the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing“ (HTI-1) Final Rule. The information about the HTI-1 Final Rule is based on the rule as published in the Federal Register, which amends provisions contained in 45 CFR 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 provisions are contained in the final rule and 45 CFR Parts 170 and 171. Please note that other Federal, state and local laws may also apply.

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

Learning Objectives

- Review the elements of information blocking
- Identify and describe the information blocking actors
- Identify and describe electronic health information (EHI)
- Identify a potential interference
- Describe enforcement roles and timeline
- Review answers to frequently asked questions
- Identify where to find more information

Request for Advisory Opinion Authority

HHS Office of the National Coordinator for Health IT
FY 2024 President's Budget: Justification of Estimates to the Appropriations Committee

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.

https://www.healthit.gov/sites/default/files/page/2023-03/FY%202024%20ONC%20508%20%28002%29.pdf

Information Blocking Definition - Updated

45 CFR 171.103:

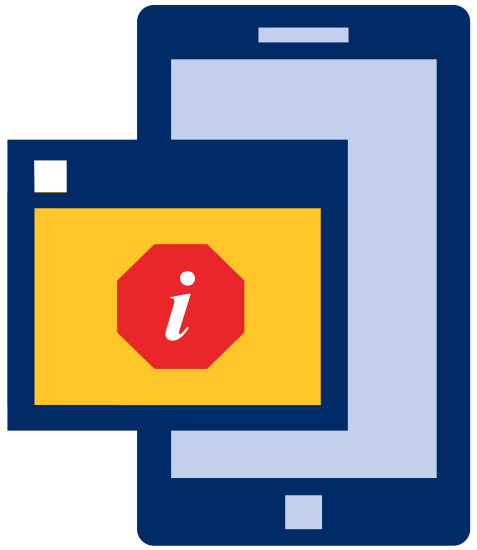
(a) Information blocking means **a practice** that **except as required by law** or covered by an exception, is likely to **interfere with** access, exchange, or use of **electronic health information** (EHI); and

(b) If conducted by:

(1) A **health information technology developer, 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

(2) 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.

Overview of Information Blocking Elements



What Makes an Individual or Entity an Information Blocker?

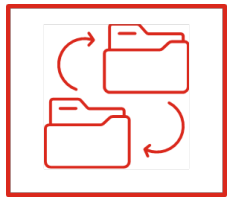
- ❑ Actor regulated by the information blocking provision
- ❑ Involves electronic health information (EHI)
- ❑ Practice is likely to interfere with access, exchange, or use of EHI
- ❑ Requisite knowledge by the actor
- ❑ Not required by law
- ❑ Not covered by an exception

Information Blocking – Am I an "Actor"?

Information blocking prohibition applies to three types of "actors"

Health Care Providers

Health IT 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

Which health care providers are covered by the information blocking regulations?

Frequent Questions
• I am a skilled nursing facility/home health entity/long term care facility/nursing facility. Am I considered a health care provider subject to the information blocking regulations?
• Is a health care provider who does not participate in Medicare or Medicaid still an “actor” under the information blocking regulations?
• Are health care providers who do not use any certified health IT subject to the information blocking regulations?

Resources:

- ONC’s Information Blocking FAQs on HealthIT.gov
- ONC Information Blocking Health Care Provider Definition Fact Sheet

Health Care Providers

42 U.S. Code § 300jj

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- rural health clinic
- ambulatory surgical center
- a therapist
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- a “covered entity” under certain statutory provisions
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Frequently Asked Questions (FAQs)

Are health care providers subject to the information blocking regulations even if they do not use any certified health IT? (ID:IB.FAQ08.1.2020NOV)

Yes, any individual or entity that meets the definition of at least one category of actor—"health care provider," "health IT developer of certified health IT," or "health information network or health information exchange" —as defined in 45 CFR 171.102 is subject to the information blocking regulations in 45 CFR part 171. The information blocking regulations in 45 CFR part 171 apply to a health care provider, as defined in the Public Health Service Act and incorporated in 45 CFR 171.102, regardless of whether any of the health IT the provider uses is certified under the ONC Health IT Certification Program.

Information Blocking – 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…."

Understanding Electronic Health Information (EHI)

Why is EHI important?

EHI is part of the information blocking definition. An actor subject to the information blocking regulations could be found to have committed information blocking if the actor engages in a practice that is likely to prevent, or materially discourage, or otherwise inhibit (interfere with) the access, exchange, or use of EHI.

How does the EHI definition align with HIPAA health care terminology?

The EHI definition incorporates terms defined in the Health Insurance Portability and Accountability Act of 1996 and the HIPAA Rules that are used in the health care industry. It focuses on a set of health information that HIPAA covered entities and business associates currently collect, maintain, and make available for access, exchange, and use. For example, EHI is a subset of the same information (i.e., the Designated Record Set) that covered entities must make available for patients to access when they exercise their HIPAA right of access.[1]

[1] To learn more about a HIPAA DRS, visit the HIPAA Omnibus Final Rule (2013), HIPAA Privacy Rule (2002), and HIPAA Privacy Rule (2000) or review relevant HIPAA FAQs that the HHS Office for Civil Rights (OCR) has issued.

Understanding Electronic Health Information (EHI)

What is Electronic Health Information (EHI)?

- 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.**

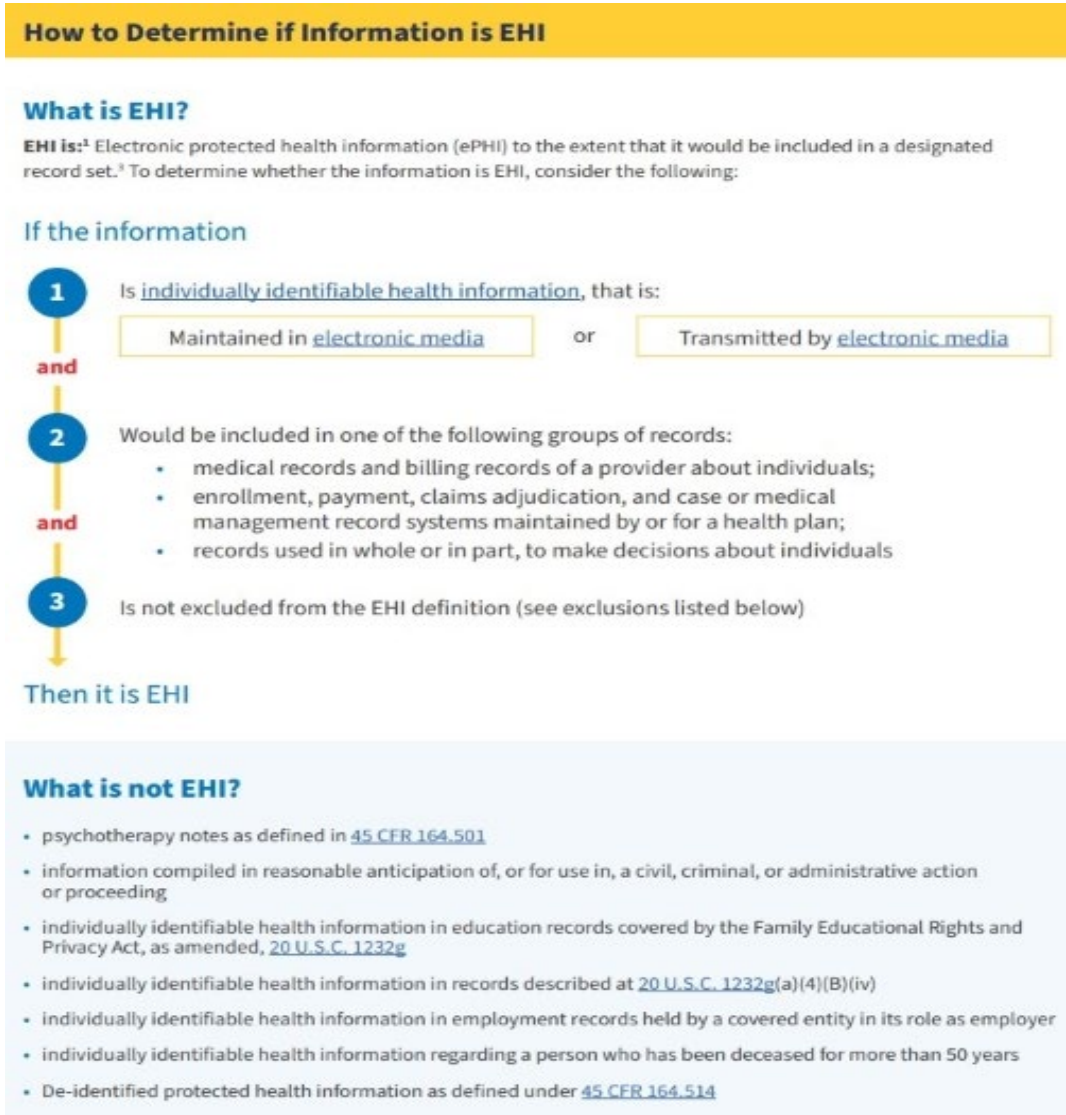
Understanding Electronic Health Information (EHI)

How do I know if my information is EHI?

In our Understanding EHI fact sheet, we have included additional information to help determine whether information is EHI.

Additional EHI Resources

- Health IT Buzz Blogs:
  - Say Hi to EHI
  - Eight Regulatory Reminders for October 6th
- Understanding EHI Fact Sheet
- Understanding EHI Infographic
- EHI FAQs
- Recorded Webinars



How to Determine if Information is EHI

What is EHI?

EHI is:[1] Electronic protected health information (ePHI) to the extent that it would be included in a designated record set.[3] To determine whether the information is EHI, consider the following:

If the information

1. Is individually identifiable health information, that is:
   - Maintained in electronic media **or** Transmitted by electronic media

and

2. Would be included in one of the following groups of records:
   - medical records and billing records of a provider about individuals;
   - enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan;
   - records used in whole or in part, to make decisions about individuals

and

3. Is not excluded from the EHI definition (see exclusions listed below)

Then it is EHI

What is not EHI?

- psychotherapy notes as defined in 45 CFR 164.501
- information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding
- individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g
- individually identifiable health information in records described at 20 U.S.C. 1232g(a)(4)(B)(iv)
- individually identifiable health information in employment records held by a covered entity in its role as employer
- individually identifiable health information regarding a person who has been deceased for more than 50 years
- De-identified protected health information as defined under 45 CFR 164.514

Frequently Asked Questions (FAQs)

Are nursing, pharmacy, or other professions' clinical notes included in the definition of "electronic health information"? (ID:IB.FAQ15.1.2021JAN)

Yes. Electronic health information (EHI), as defined in 45 CFR 171.102, does not specifically include or exclude notes or other clinical observations based on the type or specialty of the professional who authors them.

Frequently Asked Questions (FAQs)

Is electronic health information (EHI) that is covered by the information blocking regulations limited by when the information was generated? (ID:IB.FAQ20.1.2020NOV)

No, 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. On and after October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in 45 CFR 171.102, regardless of when the information was generated. For example, an actor who has the necessary technical capability to do so is required to fulfill a request to access, exchange or use EHI that they have and could appropriately disclose in response to that request even if the EHI was generated before the ONC Cures Act Final Rule was published and even if the EHI was generated before the Cures Act was enacted by Congress.

Frequently Asked Questions (FAQs)

Is an actor required to fulfill a request for access, exchange or use of EHI with all the EHI they have for a patient or should the amount of EHI be based on the details of the request? In addition, what if an actor only maintains some of the requested information electronically? (ID:IB.FAQ21.1.2020NOV)

The fulfillment of a request for access, exchange or use of EHI, including what EHI is shared, should be based on the request. However, any activity by the actor that seeks to artificially restrict or otherwise influence the scope of EHI that may be requested may constitute interference and could be subject to the information blocking regulation in 45 CFR part 171.

In terms of fulfilling requests for EHI, it is important to remember that the requirement to fulfill requests for access, exchange, and use of EHI is in any case limited to what the actor may, under applicable law, permissibly disclose in response to a particular request. Under the information blocking regulations in 45 CFR part 171, the actor is only required to fulfill a request with the requested EHI that they have and that can be permissibly disclosed to the requestor under applicable law. However, for protected health information they have, but do not maintain electronically, all HIPAA requirements would still be applicable, including the right of access.

Frequently Asked Questions (FAQs)

Do the information blocking regulations require actors to have or use certified health IT, or upgrade the certified health IT they already have, in order to fulfill a request to access, exchange, or use electronic health information? (ID:IB.FAQ06.1.2021JAN)

No. The information blocking regulations **do not** require actors to have or use health IT certified under the ONC Health IT Certification Program. Actors subject to the information blocking regulations are not required to immediately upgrade their certified health IT (as of the applicability date (i.e., April 5, 2021)) if they also happen to participate in a separate regulatory program that requires the use of certified health IT, such as CMS' Promoting Interoperability Programs.

Excerpt From ONC's "Say Hi to EHI" Blog Post


HealthITbuzz
THE LATEST ON HEALTH IT FROM ONC

Health IT Buzz > Information Blocking > Say Hi to EHI

Say Hi to EHI

Kathryn Marchesini and Michael Lipinski

The HIPAA Rules identify certain types of records that are always part of a covered entity's DRS (Designated Record Set). HHS also has issued guidance that describes some categories of information that generally would be excluded from a DRS. However, the HIPAA Rules do not specify the particular information that would make up a DRS.

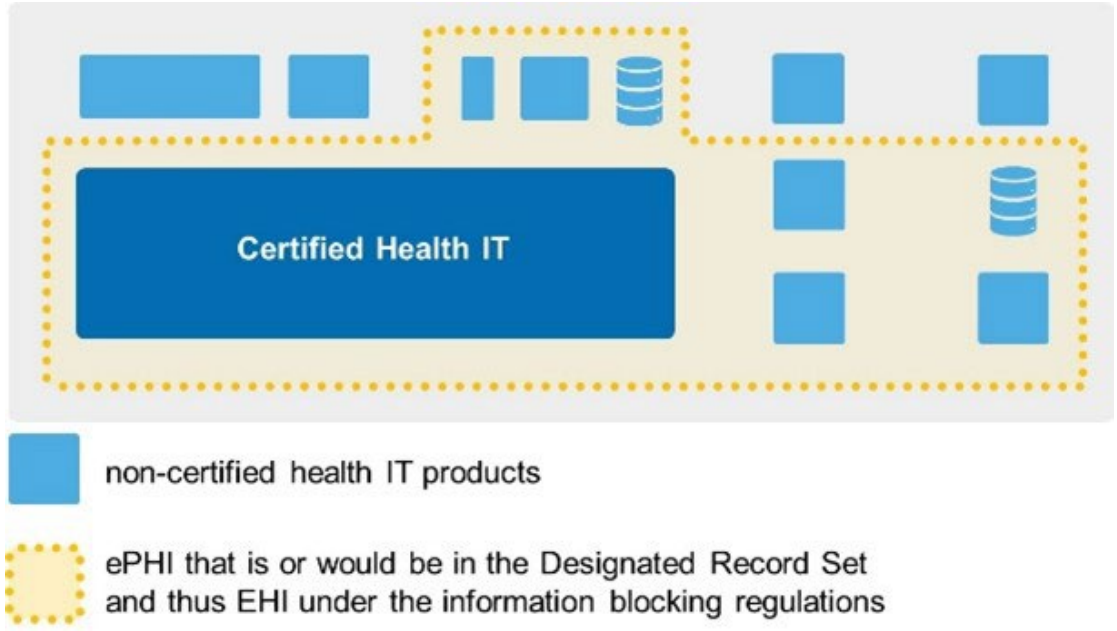
HIPAA-regulated entities should already know what information that they maintain is EHI. Since the release of the HIPAA Privacy Rule in 2000, HIPAA covered entities and their business associates have been required to identify and document which records are part of their DRS. For these entities, EHI is simply the part of the DRS that is ePHI. Because the definition of DRS is not specific to particular systems or technology platforms where an organization maintains the information, neither is the definition of EHI. EHI is not limited to what's in a certified electronic health record (EHR), for example. If actors maintain information that would be ePHI in a DRS and they were a HIPAA covered entity or business associate, then the information is EHI and subject to the information blocking regulations.

Excerpt From ONC's "Eight Regulatory Reminders" Blog Post

HealthITbuzz
THE LATEST ON HEALTH IT FROM ONC

Information Blocking: Eight Regulatory Reminders for October 6th

Steven Posnack | SEPTEMBER 30, 2022



For health care providers, in particular larger enterprises, we recognize that what's included within your DRS (Designated Record Set) may be spread out across different systems (certified or not). However, it's important to remember that your ongoing efforts to meet HIPAA Privacy Rule requirements drives what's considered EHI. One point that we've emphasized to health care providers is that "the ePHI in your DRS constitutes your EHI" for the purposes of the information blocking regulations.

The information blocking regulations do not require IB actors to adopt or use certain technologies or platforms. IB actors may use "patient portals," other web interfaces, application programming interfaces (APIs), and a multitude of technologies and platforms to make EHI available for access, exchange, or use.

Setting the Stage for Some Real-World Examples

Examples we discuss today are illustrative examples and are not a comprehensive catalog. Many other types of actions or omissions ("practices") could also implicate the information blocking provision.

A determination as to whether a "practice" would be information blocking requires a fact-based, case-by-case assessment.

Such a case-by-case assessment considers all relevant individual facts and circumstances against ***all*** the elements of information blocking.

For ease of discussion, examples focus on the likelihood of a "practice" being an "interference," but practices likely to interfere are "information blocking" only if they meet ***all*** elements of information blocking.

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 an "Actor"
- Requisite knowledge of "Actor"

What is to "interfere with," access, exchange, or use?

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

Practice Examples (illustrative purposes only) If I . . .	Unlikely to be an Interference	Likely to be an Interference *	Start to Learn More
. . .have implemented a patient portal that includes the capability for patients to directly transmit or request direct transmission of their EHI to a third party, but I choose not to enable the capability.		✓	*Practices that May Implicate Information Blocking* in the final rule and *Examples of Practices Likely to Interfere* in the proposed rule
. . . have the capability to provide same-day access to EHI in the manner requested by a patient or a patient's health care provider but choose to take several days to respond.		✓	
. . . have implemented a FHIR API that supports patients' access to their EHI via app but refuse to allow publication of the "FHIR service base URL" (sometimes also referenced as "FHIR endpoint").		✓	

* "Practices" will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor's practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Real World Examples & Likelihood of Interference

Practice Examples (illustrative purposes only) If I . . .	Unlikely to be an Interference	Likely to be an Interference *	Start to Learn More
. . . establish an organizational policy to delay the release of **all** lab results until the ordering clinician reviews the results for potential risk of harm associated with release.		✓	IB.FAQ22.1.2021MAR IB.FAQ25.1.2021JAN IB.FAQ33.1.2021JAN
. . . direct my EHR developer to configure the technology so that users cannot easily send referrals/EHI to unaffiliated providers whose Direct address the user has.		✓	Rule discussion under heading: Practices Likely to Interfere
. . . educate patients about the privacy and security risks posed by third-party apps with information that is factually accurate, unbiased, objective, fair and not deceptive, in a non-discriminatory manner.	✓		IB.FAQ27.1.2020NOV
. . . choose to provide access, exchange, or use of only those Clinical Notes authored by a physician regardless of what a patient or another provider seeks.		✓	IB.FAQ15.1.2021JAN

* "Practices" will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor's practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Real World Examples: How Much EHI, and How to Share EHI?

Practice Examples (illustrative purposes only) If I . . .	Start to Learn More
... tailor the amount of EHI that I share to what is sought, ***without*** artificially restricting or otherwise influencing the scope of EHI sought?	IB.FAQ21.1.2020NOV
. . . charge an individual, their personal representative, or another person or entity designated by the individual for *electronic access* to the individual's EHI?	ONC Cures Act Rule
… lack the technical capability to segment data the patient has refused consent to disclose from other EHI that I could permissibly disclose to another provider for treatment purposes?	ONC Cures Act Rule

Note: "Actors" have significant discretion and flexibility in determining how best to document exceptions.

* "Practices" will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor's practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Frequently Asked Questions (FAQs)

When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? (ID:IB.FAQ22.1.2021MAR)

A determination as to whether a delay would be an interference that implicates the information blocking regulation would require a fact-based, case-by-case assessment of the circumstances. That assessment would also determine whether the interference is with the legally permissible access, exchange, or use of EHI; whether the actor engaged in the practice with the requisite intent; and whether the practice satisfied the conditions of an exception. Please see 45 CFR 171.103 regarding the elements of information blocking.

***Unlikely** to be an Interference*

If the delay is *necessary* to enable the access, exchange, or use of EHI, it is ***unlikely*** to be considered an interference under the definition of information blocking (85 FR 25813).

For example, if the release of EHI is delayed in order to ensure that the release complies with state law, it is ***unlikely*** to be considered an interference so long as the delay is no longer than necessary (*see also* 85 FR 25813). Longer delays might also be possible, and not be considered an interference if no longer than necessary, in scenarios where EHI must be manually retrieved and moved from one system to another system (see, for example, 85 FR 25866-25887 regarding the manual retrieval of EHI in response to a patient request for EHI).

***Likely** to be an Interference*

It would ***likely*** be considered an interference for purposes of information blocking if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results (*see also* 85 FR 25842 specifying that such a practice does not qualify for the “Preventing Harm” Exception).

To further illustrate, it also would ***likely*** be considered an interference:

- where a delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal.
- where a delay occurs in providing a patient’s EHI via an API to an app that the patient has authorized to receive their EHI.

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

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. Manner Exception

7. Fees Exception

8. Licensing Exception

New - Exceptions that involve practices related to actors' participation in TEFCA

9. New TEFCA Manner

Information Blocking Exceptions

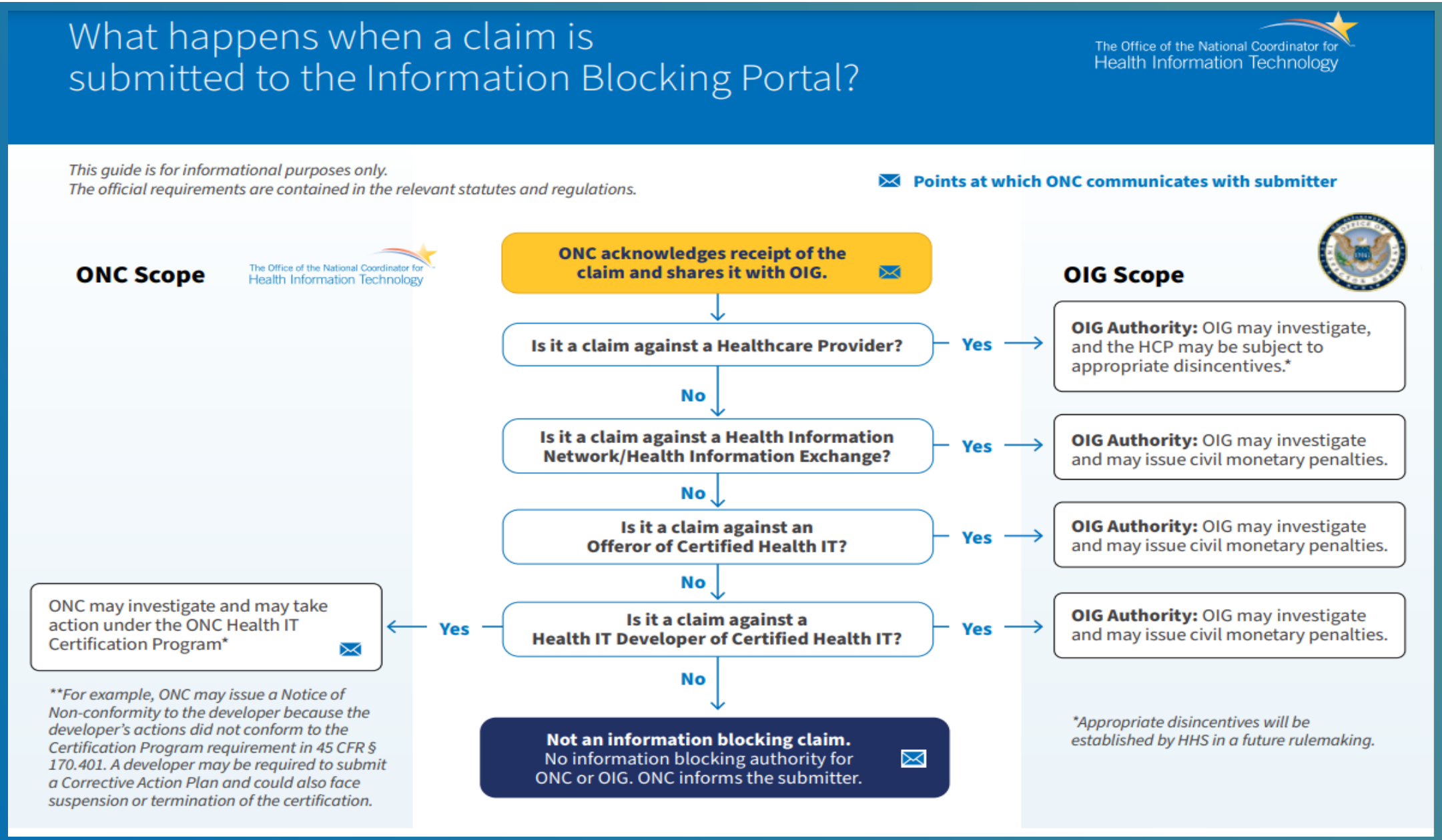
Satisfying the conditions and documenting use of an exception:

- Failure to meet an exception does not mean that an actor's practice meets the information blocking definition.
- The actor's documented records should reflect what would be needed to demonstrate the actor met each of the conditions or requirements of the exception.
  - Actors have substantial flexibility to determine where to document specific types and pieces of information — in the EHR or elsewhere in their overall records.

Information Sharing: Things to Consider

- Review your policies and processes –
  - Are they optimized for you, your staff, and your patients to access, exchange, and use EHI whenever it is legally permissible?
- Review your technology –
  - Are you making the most of its capabilities for facilitating information access, exchange, and use?
- Engage your colleagues and patients –
  - Are you talking to your developer about enhancing the capabilities?
  - Are you empowering clinical and non-clinical staff to help patients understand when and how they can choose to access their EHI?

Information Blocking Claims



https://www.healthit.gov/sites/default/files/page2/2021-11/Information-Blocking-Portal-Process.pdf

What Are the Consequences for Information Blocking?

"Actor"	Consequence
Health care providers	• Appropriate disincentives
Health information networks and Health information exchanges	• Civil monetary penalties (CMPs) up to $1 million per violation
Health IT developers of certified health IT	• Civil monetary penalties (CMPs) up to $1 million per violation • Certification action which could include a termination or ban

HHS/ONC Health Care Provider Disincentives Rulemaking

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View Rule

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HHS/ONC **RIN:** 0955-AA05 **Publication ID:** Fall 2023

Title: Establishment of Disincentives for Health Care Providers Who Have Committed Information Blocking

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act (Cures Act) to establish appropriate disincentives for health care providers determined by the HHS Inspector General to have committed information blocking. Consistent with the Cures Act, the rulemaking establishes a first set of disincentives using HHS authorities under applicable Federal law, including authorities delegated to the Centers for Medicare & Medicaid Services.

Agency: Department of Health and Human Services(HHS)
Priority: Substantive, Nonsignificant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 171 42 CFR 414 42 CFR 425 42 CFR 495
Legal Authority: 42 U.S.C. 300jj–52 42 U.S.C. 1302 42 U.S.C. 1306 42 U.S.C. 1395hh 42 U.S.C. 1395jjj 42 U.S.C. 1395rr(1) 5 U.S.C. 552.2
Legal Deadline: None

Timetable:

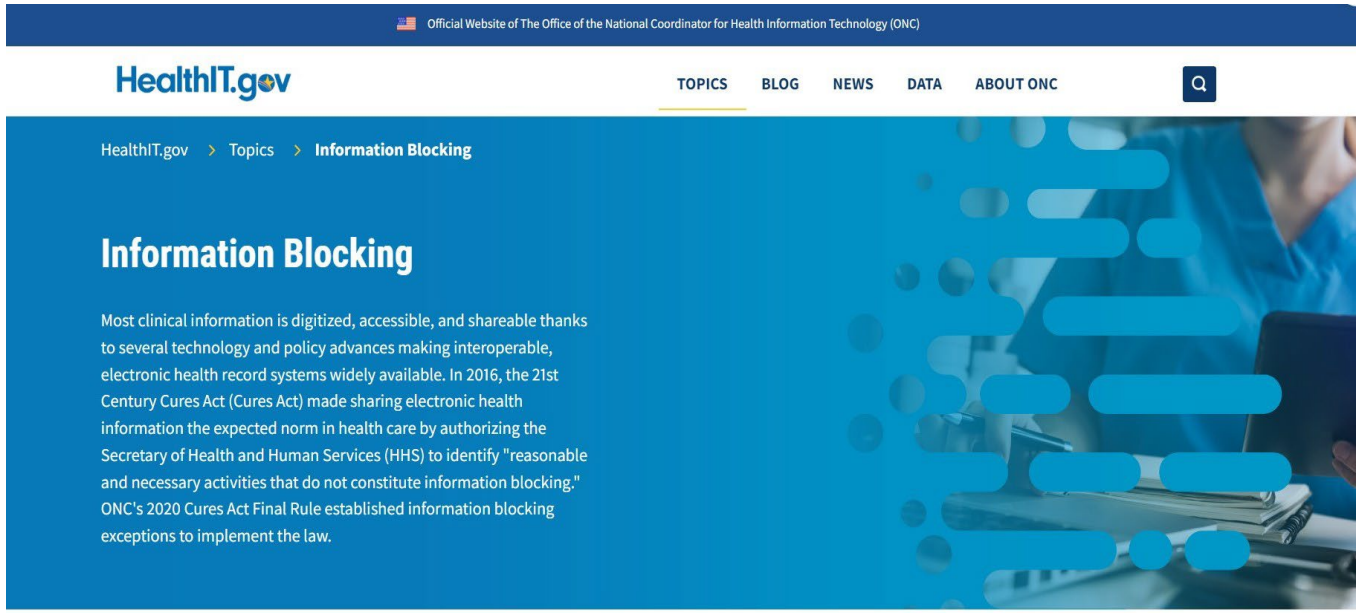
Action	Date	FR Cite
NPRM	11/01/2023	88 FR 74947
NPRM Comment Period End	01/02/2024	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=0955-AA05

Where Can You Find More Information?

Education & Outreach Resources

- https://healthit.gov/informationblocking
- Frequently Asked Questions (FAQs)
- Factsheets
- 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



Office of the National Coordinator for Health Information Technology

Contact ONC

Phone: 202-690-7151

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