

INFORMATION BLOCKING RULE



Tackling the careful balance between providing too much information and not providing enough

Dean A. McConnell



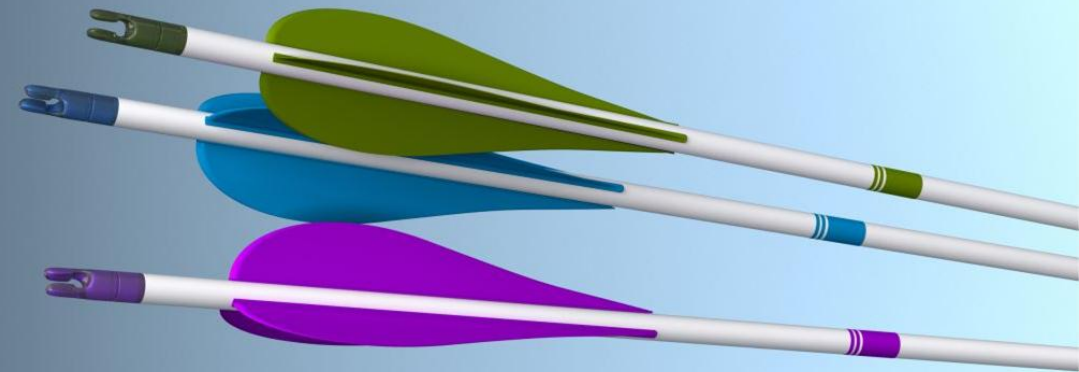
Disclosures

None of the planners, faculty, reviewers for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Objectives

This activity will:

- Demonstrate and review obligations of clinicians and non-clinicians to patients under HIPAA and the Cures Act statutes and regulations.
- Discuss recent changes, modifications and updates to the privacy and security protections for health information established under HIPAA and the CURES Act.
- Highlight key areas to ensure all those that care for patients are following HIPAA compliance rules while complying with the Cures Act.
- Illustrate and identify examples and issues where violations may occur.



The HIPAA General Rule

- Prohibits use or disclosure of Protected Health Information (medical and billing information), unless the patient (or their personal representative) has signed an authorization or unless an exception applies.



What is Information Blocking?

Paradigm Shift

Practices that are likely to interfere with the access, exchange, or use of EHI unless an exception applies.



For HCPs, knowledge that unreasonable and likely to interfere.



Who must comply?

Cures Act “Actors” include:

- Health care providers
- Health information networks or health information exchanges
- Health IT developers of certified health IT (e.g., electronic health record vendors)

HIPAA “covered entities” include:

- Health care providers
- Health Care Clearing Houses
- Health Plans

Resistance is futile



What information must be shared?

Cures Act- electronic only

- Since October 6, 2022, All electronic health information(ePHI)

HIPAA- Paper or electronic

- All protected health information (PHI) in the designated record set (medical and billing information in your records)
- HIPAA right to access, without signing an authorization



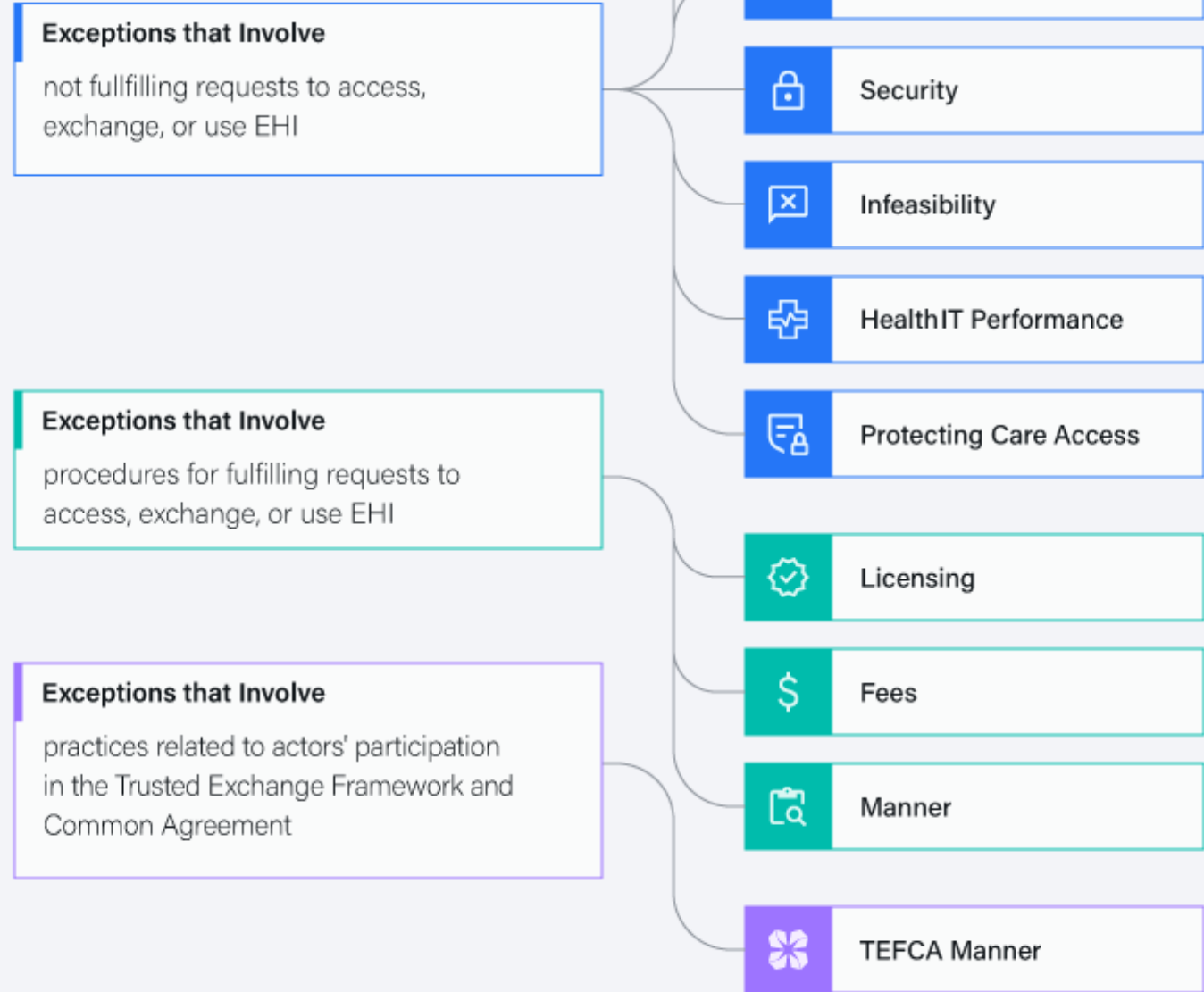
Notes to which both rules do not apply:

- **Psychotherapy notes.**
 - But not medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.
- **Work Product.**
 - Documents prepared in anticipation of litigation
- **Prohibited by law**

"We are what we are because we have been what we have been, and what is needed for solving the problems of human life and motives is not moral estimates but more knowledge."

(Sigmund Freud)

10 Exceptions to the Information Blocking Provision



When must PHI be disclosed?

Individual

Dept. of HHS



When may PHI be disclosed under HIPAA (without a patient authorization)

- treatment, payment and health care operations (TPO)
- opportunity to agree or object
 - facility directories
 - families and friends
 - deceased pt. family
- Incidental disclosures



When may PHI be disclosed (without a patient authorization)

public interest disclosures

- -required by law
- -public health activities
- -victims of abuse
- -health oversight
- -judicial and administrative proceedings
- -law enforcement
- -research
- -threats to health/safety
- -workers compensation



Preventing Harm Exception

Conditions



reasonable belief that the practice will substantially reduce a risk of harm;



no broader than necessary;



satisfy at least one condition from each of the following categories: type of risk, type of harm, and implementation basis; and



patient right to request review of an individualized determination of risk of harm.



Privacy Exception



At least one must be met:

- Precondition not satisfied: state or federal law
- Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a) (1) and (2):
 - Psych notes, work product, CLIA exempt or prohibited, certain inmate requests
- Respecting an individual's request not to share information
- ONC: "This exception recognizes that if an actor ***is permitted*** to provide access, exchange, or use of EHI under a privacy law, then the actor ***should provide*** that access, exchange, or use."

Exception 3 – Security*

It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.

- Your patient wants you to send their EHI to a personal patient portal app that you know is “currently” not secure.
 2. Tailored to specific security risks
 3. Implemented in a consistent and non-discriminatory manner
- Must either implement a qualifying organizational security policy or implement a qualifying security determination.

* Lightly edited for clarity. [Cures Act Final Rule: Information Blocking Exceptions \(healthit.gov\)](https://www.healthit.gov/act/cures/cures-act-final-rule-information-blocking-exceptions)

Exception 4 – Infeasibility*

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.

- The system is unavailable due to an Internet outage.
- The records are part of a data set that includes protected information that cannot be redacted.
- The records were purged from the system 10 years ago.
- A minor's records cannot be segmented.

certain factors that make complying with the request infeasible under the circumstances.

Must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible.

* Lightly edited for clarity. [Cures Act Final Rule: Information Blocking Exceptions \(healthit.gov\)](https://www.healthit.gov/2015/09/24/cures-act-final-rule-information-blocking-exceptions)

Exception 5 – H.I.T. Performance*

It will not be information blocking for an actor 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.

- You have taken the database offline to perform necessary system maintenance.
- You have temporarily removed access by users in order to troubleshoot a possible malware incursion.

An actor may take action against a third-party app that is negatively impacting the health IT's performance, provided that the practice is:

1. For a period of time no longer than necessary to resolve any negative impacts;
 2. Implemented in a consistent and non-discriminatory manner; and
 3. Consistent with existing service level agreements, where applicable.
- If the unavailability is in response to a risk of harm or security risk, the actor must only comply with the Preventing Harm or Security Exception, as applicable.

* Lightly edited for clarity. [Cures Act Final Rule: Information Blocking Exceptions \(healthit.gov\)](https://www.healthit.gov/CuresActFinalRule/InformationBlockingExceptions)

Exception 6 – Protecting Care Access (Reproductive Health)

- **It is not information blocking to decline to produce Reproductive Health information, if**
 - Information requested pertains to a person seeking, obtaining, providing or facilitating lawful reproductive health care (broadly defined to include any information relating to the reproductive system including not only abortion, but contraception, STIs, and peri or post menopause care).
 - Good faith belief that providing information would “potentially expose” a person to legal action (criminal, civil or administrative).
 - Declining to provide information is likely to reduce the risk of litigation.
- **Corresponding HIPAA regulations invalidated by court (6/2025)**
- **Current administration may repeal**

Exception 7 – Content & Manner

It will not be information blocking for an actor 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.

- *Content Condition*

- Requires a discussion.

- Your EHR vendor cannot produce all the information requested (e.g., x-ray image); however, it can produce the “minimum data set.”

- Your EHR vendor cannot produce the information in the format requested, however, it can produce it in some form.

- *technically unable to fulfill the request in the manner requested, or*

- *Cannot reach agreeable terms with the requestor to fulfill the request*

- *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.*

Exception 8 – Fees

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

- Applies to “development of technologies and provision of services that enhance interoperability”
- Your fee represents your documented, actual costs of copying records.
- Cannot charge a fee for electronic access or transfer.
- Your fee structure is the same for all requestors.

- *Comply with Conditions of Certification in § 170.402(a)(4) (Assurances – certification to “EHI Export” criterion) or § 170.404 (API)*

Exception 9 – Licensing

It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

- *Negotiating conditions: Begin license negotiations with the requestor within 10 business days from receipt of the request and negotiate a license within 30 business days from*

- **Your EHR vendor charges a fee for supporting a Portal through which you can deliver EHI.**

- *Non-discriminatory terms*
- *Collateral terms*
- *Non-disclosure agreement*
- *Additional conditions relating to the provision of interoperability elements.*

Exception 10 – Trusted Exchange Framework and Common Agreement (TEFCA)

It will not be information blocking for an actor to fulfill certain requests for access, exchange, or use of EHI only via TEFCA (A network of networks), provided certain conditions are met. TEFCA was created to remove barriers for sharing health records electronically among healthcare providers, patients, public health agencies, and payers.

The exception applies only where:

- The actor and requestor are both part of TEFCA (signed Common Agreement);*
- Access, exchange, or use of the requested EHI can be supported via TEFCA for both the actor and requestor;*
- The request for access, exchange or use is not via API standards adopted under the ONC Health IT Certification Program;*
- Any fees charged and any licensing of interoperability elements by the actor in relation to fulfilling the request via TEFCA satisfy, respectively, the Fees Exception (§ 171.302) and Licensing Exception (§ 171.303).*

Information Blocking Examples

Routine delays in posting **lab results** until after physician speaks with the patient.

Requiring an individual's **written consent** before sharing with unaffiliated providers for **treatment** purposes even though not required by state or federal law

Failing to provide **same-day access** to EHI in a form and format requested by a patient or a provider but takes **several days to respond**

Not enabling **patient portal** feature that allows patients to directly transmit or request direct transmission of their EHI to a third party

Incorrectly claiming HIPAA or other laws preclude exchanging EHI with **unaffiliated providers**

When **switching to another EHR** system, the **developer will provide only the EHI in a PDF format**

A health system insists that local physicians adopt its EHR platform, which provides **limited connectivity** with competing hospitals and facilities.

A hospital directs its EHR developer to configure its technology so that users cannot easily send electronic patient **referrals** and associated EHI to unaffiliated providers

Consider it “social media”



Clinical information may become exposed on social media



Writing, vocabulary and style need to be impeccably professional



As for past records, well...

Resources

- <https://www.dwt.com/insights/2020/04/onc-cms-interoperability-final-rules>
- [Information Blocking | HealthIT.gov](https://healthit.gov/information-blocking/) | fact sheets and FAQs
(<https://healthit.gov/information-blocking/>)
- [New information-blocking rules: What doctors should know | American Medical Association \(ama-assn.org\)](https://www.ama-assn.org/practice-management/digital/new-information-blocking-rules-what-doctors-should-know): <https://www.ama-assn.org/practice-management/digital/new-information-blocking-rules-what-doctors-should-know>



**Questions?
Thanks!**