

INFORMATION BLOCKING: WHAT PSYCHIATRISTS NEED TO KNOW

BACKGROUND

For decades the federal government has been trying to move patient health records from a paper-based system to an electronic one. The goal of interoperability – information flowing seamlessly between providers, patients, and payers – has yet to be achieved. To further the government’s goal of removing barriers to allow the free flow of information (thereby minimizing information blocking), various laws have been enacted, with a focus on preventing information blocking with patients (interfering with the patient’s right to access their own information), including the following four:

1. Cures Act Final Rule on Information Blocking (see next section below for detailed information)

Source: ONC – the Office of the National Coordinator for Health Information Technology

Applies to: “Actors” – healthcare providers (specifically including physicians) with electronic health information (EHI), Health Information Networks (HINs) or Health Information Exchanges (HIEs), and health IT developers of certified health IT

Requires: EHI must be provided to patients when requested, unless a specific exception applies; interfering with patient requests for access is prohibited

Compliance: Required as of “applicability” date of April 5, 2021; however, the enforcement details have not been published by the OIG

Key Points to Remember:

- Information blocking can occur in many different situations, such as providers trying to access records of other providers, providers trying to migrate from one EHR system to another, and patients trying to access their own records or have them sent to another provider
- This regulation does not increase a patient’s right of access; it only makes it easier for patients to access information that they already have a right to see
- The “open notes” movement generally means patients having immediate access to notes of their visits
- This regulation only applies to EHI
- This regulation applies to all providers with EHRs, regardless of whether the EHR is certified by ONC
- You are not required to have an EHR, or any other EHI
- You are not required to have a certified EHR
- This regulation applies to all providers with EHI, even those who are not a covered entity under HIPAA
- There is no requirement to proactively provide EHI; providers with EHI must respond to requests received
- The government’s ultimate stated goal is for patients to be able to connect with providers’ EHRs via apps
- Other laws (such as HIPAA, 42 CFR Part 2, and state law) are still applicable. As stated by the AMA, ONC’s Final Rule “is not meant to require disclosure of EHI in any way that would be impermissible under HIPAA. Yet, if [a physician] is **permitted** to disclose EHI under HIPAA, they are **now required** to do so to avoid potential information blocking violations – subject to the exceptions...” ([AMA Summary](#))
- There are many unanswered questions under this extensive, complex regulation. We have posed several questions to ONC requesting guidance. We hope to provide additional information as answers are received.

- There are no enforcement details yet for physicians.

For more information, see page 3.

2. HIPAA's Privacy Rule

Source: OCR - the Office for Civil Rights

Applies to: Covered entities, including physicians who meet the definition under HIPAA ([Covered Entity Guidance tool](#))

Requires: Protected health information (PHI), paper and electronic, must be provided to patients, with very limited exceptions. OCR has aggressively enforced this requirement under its patient Right of Access Initiative. Also, if requested by the patient, covered entities must provide electronic copies of the patient record (both paper and electronic) if it is feasible and reasonable to do so. See OCR's [Individuals' Right under HIPAA to Access their Health Information](#).

Compliance: Required as of April 2003

For more information, see [Patient Rights Under HIPAA, Privacy Rule summary](#).

3. Interoperability and Patient Access Final Rule

Source: CMS – Centers for Medicare and Medicaid

Applies to: Hospitals and CMS-regulated payers

Requires: Among other things, hospitals must send electronic patient event notifications of a patient's admission, and/or discharge, and/or transfer to another healthcare facility or to another community provider

Compliance: Varies by provision

For more information, see CMS' [Interoperability and Patient Access Fact Sheet](#).

4. State Law Regarding Patient Access

Source: State legislature and/or state licensing board

Applies to: Everyone practicing in the state

Requires: Requirements vary by state, but typically patients have the right to access their record; any exceptions to this right are very limited. States can also require release of patient records in electronic form (even paper records) if possible.

For more information, see the relevant state's law.

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WHAT IS ONC'S CURES ACT FINAL RULE ON INFORMATION BLOCKING?

In May 2020, The Office of the National Coordinator for Health Information Technology (ONC) issued its Final Rule to implement interoperability and access requirements outlined in the 21st Century Cures Act of 2016. ONC's Cures Act Final Rule is designed to promote patient access to electronic health information across the industry.

Government's Goal: Patients Have Access to Their Records

Paper and Electronic Information

For health information in all forms - paper and electronic:
Individuals have the right to access their information under
state and federal law (such as HIPAA)

Electronic Information

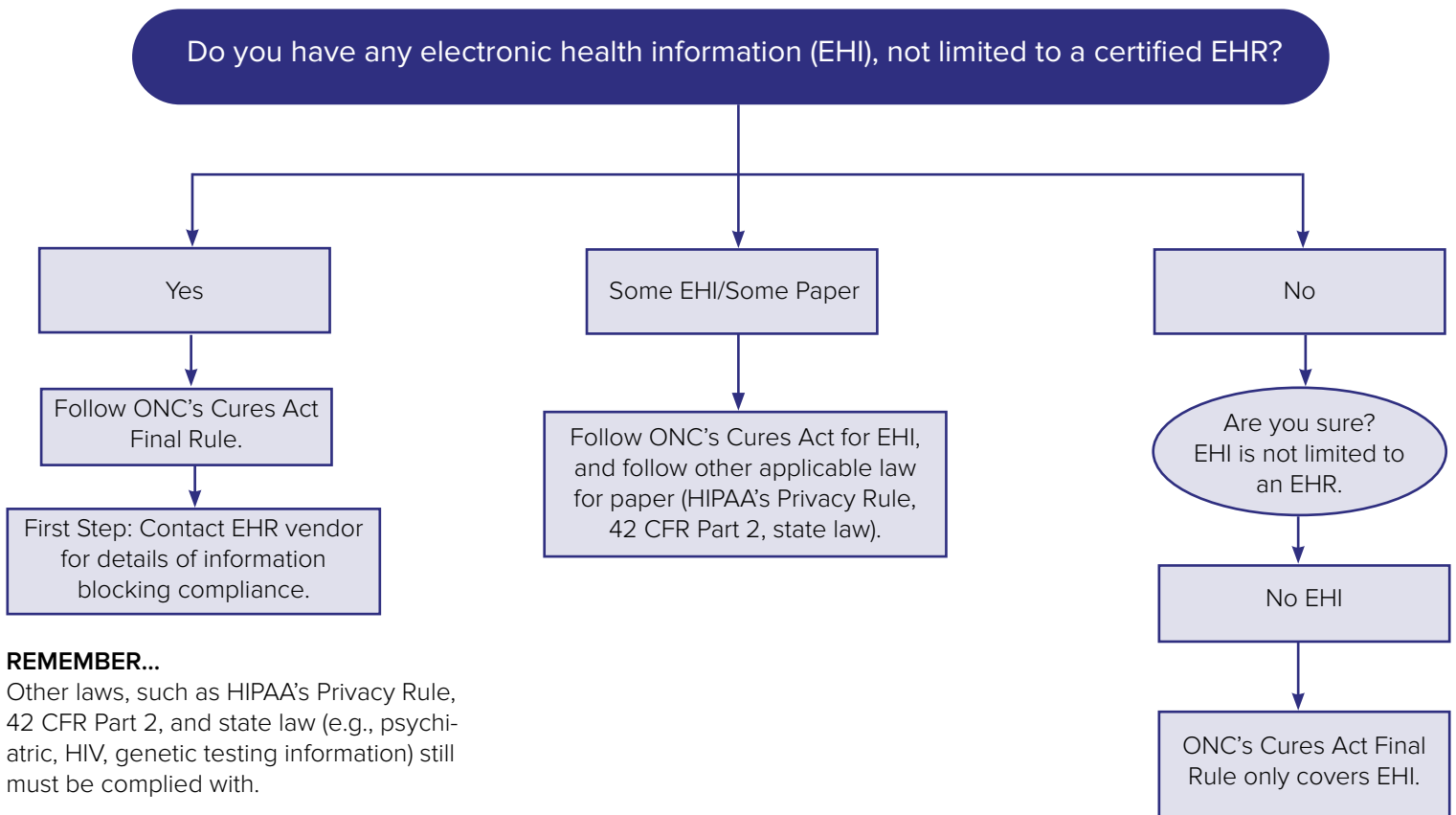
For health information in electronic
form: The new information
blocking regulation addresses
patient access to electronic health
information and fee limits

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DOES ONC'S CURES ACT FINAL RULE APPLY TO ME?

While all practicing physicians are technically “actors” under the [definition](#), only those with any EHI are subject to the information blocking regulation.

Sharing Electronic Health Information with Patients



REMEMBER...

Other laws, such as HIPAA's Privacy Rule, 42 CFR Part 2, and state law (e.g., psychiatric, HIV, genetic testing information) still must be complied with.

HOWEVER...

Patients still have the right to access copies of their paper records under state law and other federal law, such as 42 CFR Part 2 and HIPAA's Privacy Rule. OCR is aggressively enforcing patients' right of access under HIPAA. Access to paper records may involve having to convert the paper record into an electronic copy, if requested by the patient, and if it can reasonably be done (e.g., HIPAA, and possibly, state law).

WHAT IS EHI?

Until October 5th, 2022, electronic health information (EHI) is defined as any electronic data that falls within the [United States Core Data for Interoperability \(USCDI\)](#).

- Under the USCDI, EHI is limited to the following categories of electronic data:
 - Allergies and Intolerances
 - Assessment of Plan and Treatment
 - Care Team Members
 - Goals
 - Health Concerns
 - Immunizations
 - Laboratory
 - Medications
 - Patient Demographics
 - Problems
 - Procedures
 - Provenance
 - Smoking Status
 - Unique Device Identifiers for a Patient's Implantable Device
 - Vital Signs
 - **Clinical Notes** (structured field or free text data), which include:
 - Discharge Summary Notes
 - History & Physicals
 - Progress Notes
 - Consultation Notes
 - Imaging Narratives
 - Laboratory Report Narratives
 - Pathology Report Narratives
 - Procedure Notes

As of October 6, 2022, the definition of electronic health information (EHI) will expand to [electronic protected health information](#) (ePHI as defined by HIPAA).

Electronic Health Information (EHI) EXCLUDES:

- [Psychotherapy Notes](#) (as defined by HIPAA):
Notes recorded (in any medium) by a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are SEPARATED from the rest of the individual's medical record. Psychotherapy notes **exclude**:

- Medication prescription and monitoring
- Counseling session start and stop times
- The modalities and frequencies of treatment furnished
- Results of clinical tests
- Any summary of the following items:
 - Diagnosis
 - Functional status
 - The treatment plan
 - Symptoms
 - Prognosis
 - Progress to date

Key points to remember about psychotherapy notes:

- OCR views psychotherapy notes as process notes – separate from the rest of the record and containing information of no value to anyone other than the provider who created the notes. (For more information, see [OCR's comments](#) – beginning at page 82623)
- Under federal law, psychotherapy notes are not accessible by patients directly; however, patients have the right to have the psychotherapy notes released to others.
 - Under state law, patients may have access to psychotherapy notes directly
- Psychotherapy notes may be ordered to be released by a court
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
- Deidentified data

WHAT IS INFORMATION BLOCKING?

A physician is information blocking if the physician conducts a practice (act or omission) which they know¹:

- Is likely to interfere with (prevent, materially discourage, or otherwise inhibit) access, exchange, or use of electronic health information, AND
- Is unreasonable.

Information blocking EXCLUDES:

- Practices required by state or federal law.
 - For example, there are very strict requirements under 42 CFR Part 2 for the release of drug and alcohol treatment records
- Practices covered by one of the eight information blocking exceptions (see below)

Examples likely to be considered information blocking²:

- A physician implements formal restrictions on the access, use, or exchange of EHI:
 - The physician's internal policies or procedures require staff to obtain an individual's written consent before sharing patient's EHI with unaffiliated providers for treatment purposes even though obtaining an individual's consent is not required by state or federal law.

- A physician informally restricts the access, use, or exchange of EHI:
 - A physician incorrectly claims that the HIPAA Rules preclude it from exchanging EHI with unaffiliated providers.
- A physician limits the interoperability of EHI:
 - Although an EHR’s patient portal offers the capability for patients to directly transmit or request for direct transmission of their EHI to a third party, the physician using the EHR chooses not to enable this capability.
 - A physician has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient’s healthcare provider, but takes several days to respond.

According to the [AMA](#), high-risk information blocking activities may involve interfering with:

- 1) Patient access to EHI
- 2) Providers seeking EHI from other providers for treatment
- 3) Payers seeking EHI
- 4) Patient safety

WHAT ARE THE EIGHT EXCEPTIONS TO INFORMATION BLOCKING?

Eight Information Blocking Exceptions	
Exceptions That Involve Not Fulfilling EHI Requests	
Preventing Harm Exception	Not information blocking if a physician engages in practices that are reasonable and necessary to prevent harm to a patient or another person, PROVIDED CERTAIN CONDITIONS ARE MET.
Privacy Exception	Not information blocking if a physician does not fulfill an EHI request in order to protect an individual’s privacy, PROVIDED CERTAIN CONDITIONS ARE MET.
Security Exception	Not information blocking if a physician interferes with access, exchange, or use of EHI in order to protect the security of EHI, PROVIDED CERTAIN CONDITIONS ARE MET.
Infeasibility Exception	Not information blocking if a physician does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, PROVIDED CERTAIN CONDITIONS ARE MET.
Health IT Performance Exception	Not information blocking if a physician takes 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.
Exceptions That Involve Procedures for Fulfilling EHI Requests	
Content and Manner Exception	Not information blocking if a physician limits 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.
Fees Exception	Not information blocking if a physician charges fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, PROVIDED CERTAIN CONDITIONS ARE MET.
Licensing Exception	Not information blocking if a physician licenses interoperability elements for EHI to be accessed, exchanged, or used, PROVIDED CERTAIN CONDITIONS ARE MET.

Review of Physician’s Denial of Access Based on Risk of Harm Exception:

If a physician denies access to a patient based on the risk of harm exception, the patient has the right to request review of an individual determination of risk of harm precluding access. In the comments section of the Final Rule, ONC discusses the requirement for both Covered Entities under HIPAA and those not covered by HIPAA as follows:

For those covered by HIPAA:

- HIPAA §164.524(a)(4) specifically provides for the review of determinations made by physicians in the exercise of professional judgment, so follow the HIPAA requirements.

For those not covered by HIPAA:

- Physicians' practices must be consistent with any rights of review of individual determinations of risk of harm that patients may be afforded under applicable federal, state, or tribal law.

Key points to remember:

- Before relying on any of the exceptions listed above, be sure to review the exception's conditions. In order to satisfy an exception, a physician must meet all of the applicable conditions of the exception.
- Failure to meet the conditions of an exception does not automatically mean a practice constitutes information blocking. The specific facts and circumstances would still be assessed on a case-by-case basis to determine if the practice rises to the level of an interference.
- Documentation – If you choose to rely on one of the eight exceptions to information blocking, you should document the basis for that exception.

RELEASING EHI

Upon request, release EHI without delay: Unless you are otherwise legally prohibited from providing the requested EHI or one of the eight exceptions applies, EHI should be released upon request without delay.

Proactive Release Not Required: There is no requirement under the information blocking regulations to proactively make EHI available to those who have not requested EHI. However, a delay in the release or availability of EHI in response to a request may constitute an interference under the information blocking regulations.

(See "Interference" heading under [ONC's Information Blocking FAQs](#).)

FEES FOR PATIENT ACCESS

If patients access their EHI electronically, then no fee can be charged. "Electronic access" is defined as "Internet-based method that makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request." Examples of electronic access for which patients cannot be charged include accessing EHI via a patient portal, an app, or other internet-based means – no manual effort is involved to meet the request at the time of the request.

If there is manual labor required for the patient to access EHI, fees a physician may charge are limited by HIPAA and state law. Examples of electronic access requiring manual labor include transferring EHI onto a flash drive, CD, etc.

As always, other relevant laws must be complied with. For example, states can require that patients be provided a copy of their record at no charge ([KY for example](#)). And OCR acknowledges that patients may be charged under HIPAA's Privacy Rule, but strongly encourages covered entities not to charge patients for copies of their record. According to [OCR's Guidance on Individual's Right under HIPAA to Access their Health Information](#), "...while the Privacy Rule permits the limited fee..., covered entities should provide individuals who request access to their information with copies of their protected health information free of charge."

ENFORCEMENT

There are six basic elements necessary to support an information blocking claim:

- 1) Physician
- 2) Interference with access, use, or exchange of
- 3) EHI
- 4) Intent by the physician
- 5) The practice alleged to be information blocking isn't required by law
- 6) The practice alleged to be information blocking falls outside one of the eight information blocking exceptions

Note: There is no requirement to show that a physician harmed the requesting party.

While the penalties are clear for violations of this rule by health IT developers and health information networks/exchanges, we do not know enforcement details for physicians. We know that physicians determined by the HHS Office of the Inspector General (OIG) to have committed information blocking will be referred to the appropriate agency to be subject to “appropriate disincentives” under existing authority. The OIG will be publishing enforcement details for physicians in the future.

(See “Enforcement” heading under [ONC’s Information Blocking FAQs](#).)

IF YOU OWN AN EHR, YOUR FIRST STEP SHOULD BE...

The first step is to contact your EHR vendor to discuss how your system allows you to meet the requirements of ONC’s information blocking rule. If your vendor tells you the information blocking rule doesn’t apply to their non-certified EHR, that may be correct; however, the information blocking rule does apply to physicians that maintain EHI, regardless of whether their EHR is certified under ONC’s certification program or not (see “Actors” heading under [ONC’s Information Blocking FAQs](#)).

ADDITIONAL RESOURCES

American Medical Association:

- [Part 1: What is Information Blocking?](#)
- [Part 2: How Do I Comply with Info Blocking and Where Do I Start?](#)
- [Summary of the ONC Rule](#)

American Psychiatric Association:

- [APA Webinar: Information Blocking Overview](#)

College of Healthcare Information Management Executives

- [Summary of Information Blocking and Eight Exceptions](#)

Office of the National Coordinator for Health Information Technology

- [ONC Cures Act Final Rule Resources](#)

¹ 45 C.F.R. § 171.103

² 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642-01 (May 1, 2020).