APTA Practice Advisory: Information Blocking

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The issue: New rules regarding information blocking take effect April 5, 2021. The 21st Century Cures Act defined information blocking as practices that are likely to interfere with access, exchange, or use of electronic health information. The U.S. Department of Health and Human Services has the responsibility for implementation. The info blocking regulations apply to health care providers, health IT developers of certified health IT, and health information exchanges and networks.

What you need to know: On April 5, 2021, new regulations take effect to improve the sharing of electronic information with patients and between organizations. This is a positive development for person-centered care, but it also increases the importance of physical therapists and physical therapist assistants understanding these regulations to remain compliant and avoid potential penalties or disincentives for info blocking violations. Consequences of noncompliance may include penalties and disincentives. (See page 4.)

Suggested next steps: This advisory provides recommendations for practice owners and organization administrators, staff PTs and PTAs, and health IT developers. Review this advisory in detail, paying close attention to definitions and tips for compliance. Also review APTA's other resources on information blocking. (See page 8.) Share this information with your colleagues.

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APTA issues practice advisories to assist the physical therapy community in providing quality care that follows best available evidence and practice management principles. Practice advisories are not formal association guidelines, policies, positions, procedures, or standards. They are not clinical practice guidelines and do not establish a standard of care.

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Information Blocking: Background

The 21st Century Cures Act of 2016 prohibited information blocking and directed the U.S. Department of Health and Human Services to issue related regulations. In 2020, the HHS Office of the National Coordinator for Health Information Technology — known as ONC — released info blocking regulations designed to make information available to patients and requesters as soon as possible with as few extra steps as needed.

Cures Act Final Rule

According to the law, information blocking is a practice that, unless it is required by law or specified by the HHS Secretary, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. For health information technology developers, exchanges, or networks, their actions are considered info blocking if, they know, or should know, that the practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information. For individual or institutional health care providers, their actions are considered info blocking if they know that the practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Abbreviation Index

- APM: Advanced Payment Model
- CEHRT: Certified Electronic Health Record Technology
- CMS: Centers for Medicare & Medicaid Services
- EHI: Electronic Health Information
- EHR: Electronic Health Record
- HHA: Home Health Agency
- HHS: U.S. Department of Health and Human Services
- HIN: Health Information Network
- HIE: Health Information Exchange
- HIPAA: Health Insurance Portability and Accountability Act
- MIPS: Merit-based Incentive Payment System
- ONC: Office of National Coordinator for Health Information Technology
- ePHI: Electronic Protected Health Information

The rule refers to the various entities subject to info blocking rules as "actors." This includes both HIPAA-covered entities and non-covered entities. Keep in mind that you might qualify as more than one type of actor.

Engaging in info blocking can lead to disincentives, financial penalties, or both, depending on who you are, although the HHS Office of Inspector General hasn't finalized the rules regarding the financial penalties, and ONC hasn't yet established the info blocking disincentives for providers. There also are exceptions to the rule. If you qualify for one or more of them, you will not be subject to penalties or disincentives.

You can review the info blocking regulations at 45 C.F.R. Part 171.

Understanding Terminology: "Electronic Health Information" Now and in 2022

Even though the Cures Act prohibited info blocking of electronic health information, it didn't define EHI. In its regulations, ONC adopted a broad definition of EHI, but that broad definition won't be put in place until Oct. 6, 2022. In the meantime, ONC adopted a narrower definition of EHI, limiting it to the information represented in the data classes included in the United States Core Data for Interoperability, also known as USCDI.

USCDI is a standardized set of health data classes and data elements for health information exchange. USCDI contains a set of 16 data classes:

- Allergies and Intolerances
- Assessment and Plan of Treatment
- Care Team Members
- Clinical Notes
- Goals
- Health Concerns
- Immunization
- Laboratory
- Medications

- Patient Demographics
- Problems
- Procedures
- Provenance (such as when and who created the data)
- Smoking Status
- Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Vital Signs

Many of the data classes contain multiple individual data elements. The Vital Signs class, for example includes a range of measurements such as blood pressure, respiratory rate, and pulse oximetry, all of which must be provided to patients upon request. The Clinical Notes class includes consultation notes, discharge summary notes, history and physical notes, imaging narratives, laboratory report narratives, pathology report narratives, procedure notes, and progress notes.

By using USCDI as the baseline of EHI until October 2022, ONC hopes to create a starting point for sharing the types of EHI that are well understood and more readily available for sharing and use.

The broader definition of EHI that comes into play Oct. 6, 2022, will include electronic protected health information included in a designated record set as defined by HIPAA. This includes not only the information included in the USCDI, but also data within a designated record set — medical and billing records, payment and claims adjudication information maintained by or for a health plan, and other records used to make decisions about individuals.

Under the information blocking regulations, you are only required to fulfill a request with the EHI that you have and that can be permissibly disclosed under applicable law. For protected health information you have but do not maintain electronically, all HIPAA requirements are still applicable, including the right of access.

Complying With the Rules

How to comply with the info blocking rules is similar across "actor" types, but there are differences. Depending on the type of actor you are, what you need to know will vary. The information below is intended to serve as a guide only; consult with an attorney for specific guidance and application to your circumstances.

Practice Owner or Organization Administrator: What You Need to Know

Actor type: Health care provider or HIN/HIE

- **You are subject to info blocking rules** and can be held responsible for failing to respond to a request for EHI. This applies to both HIPAA-covered and non-covered entities.
- **You must respond in a timely manner** once you receive a request to access, exchange, or use EHI. Delays or other unnecessary impediments could implicate the info blocking provisions.
- **You must know and understand the eight exceptions** to info blocking.
- **You are required to respond to requests for EHI under the info blocking rule even if you do not use an EHR that satisfies the certified technology (CEHRT) requirements.**

Responding to Requests for EHI

- **Determine whether your health IT developer's EHR (EHR vendor) will enable you to send requested EHI content in a timely fashion and in the manner requested.** Identify any potential limitations in your EHR. Make sure your health IT developer has a plan in place to distinguish between data elements included in the USCDI and other EHI included in the EHR for purposes of responding to requests for EHI.
- **Ask your health IT developer how they will help you determine and document the use of an exception.**
- **Review and update your vendor and business associate agreements** to make sure they are designed to help you respond to requests for EHI. See: APTA Analysis: Complying with Information Blocking Rules.
- **Familiarize yourself with the U.S. Core Data for Interoperability.** EHRs store information that corresponds to the data elements of the USCDI (electronic health information about the patient).
- **Between April 5, 2021 and Oct. 5, 2022,** you are required to share the scope of EHI included within USCDI (if legally permissible to share).
- **After Oct. 5, 2022, this expands to ePHI included in a designated record set.**

Financial and Administrative Implications

- **If you do not adequately respond to a request for EHI, you may be accused of info blocking**, which has negative financial and administrative implications.

Quality Payment Program

- **Familiarize yourself with the Quality Payment Program and monitor changes to it.**
- **CMS requires MIPS-eligible clinicians to use certified EHR technology to meet requirements of the Promoting Interoperability category. Physical therapists** have been exempted from the PI category because there are few PT-specific EHR products that are CEHRT. To advance interoperability and exchange of standardized data, it's expected that CMS will require PTs to participate in the PI category in the future.
- **Not using CEHRT will limit your participation in Advanced APMs and other value-based payment model opportunities**, which may make it more difficult to successfully participate in MIPS, may increase your burden in sharing or receiving EHI, and may impact your referral sources, as they expect other health professionals to be using interoperable EHRs, just as they do.

Recommendations

- **Evaluate and verify how your health IT developer will support you in responding to requests for EHI.** If the health IT developer is not subject to info blocking, determine how this may or may not impact your ability to respond to requests for EHI.
- **Ask your health IT developer the following questions:**
    1. Do you develop certified health information technology and thus are subject to the info blocking rules?
    2. How will you support me in responding to requests to access, exchange, or use EHI?
    3. What are your plans to certify your product(s), if any?
    4. How will pursuing certification impact the cost of the product to me, the client?

Staff PTs and PTAs: What You Need to Know

Actor type: Health care provider

- **Therapists are subject to info blocking rules** and can be held responsible for failing to respond to a request for EHI.
- **You must respond in a timely manner** once a request to access, exchange, or use EHI is made. Delays or other unnecessary impediments could implicate the info blocking provisions.
- **You must know and understand the eight exceptions** to info blocking.

Recommendations

- **Familiarize yourself with your employer's policies and procedures** that govern how to handle a request to access, exchange, or use EHI from a patient, provider, or other legitimate requester. If you have no policies and procedures, encourage your practice owner or administrator to develop them.
- **Familiarize yourself with the USCDI.** EHRs store information that corresponds to the data elements of the USCDI (electronic health information about the patient).
- **Know that between April 5, 2021, and Oct. 5, 2022, an actor is required to share the EHI** included within USCDI (if legally permissible), and prepare for the change that comes on **Oct. 6, 2022**, which expands the rule to electronic PHI included in a designated record set.

Health IT Developer: What You Need to Know

Actor type: Health IT developer of certified health IT

- **The info blocking rules apply to a developer of certified health IT**, not the product itself.
- **You are subject to the info blocking rules if just one of your multiple products is certified**, regardless of whether the product involved is certified or not.
- **You must know and understand the eight exceptions** to info blocking.
- **Consider how you can support your clients** in identifying when an exception may be applicable.

Responding to Requests for EHI

- **Reach out to your clients** and explain whether you're considered a certified health IT developer subject to info blocking, even if the EHR software isn't certified.
- **Explain to your clients how you will support them in responding to EHI requests** in a timely fashion and in the manner requested, even if you're not a certified health IT developer.

Quality Payment Program

- **Familiarize yourself with the Quality Payment Program** and monitor changes to it.
- **CMS requires MIPS-eligible clinicians to use certified EHR technology to meet requirements of Promoting Interoperability category.** Physical therapists have been exempted from the PI category because there are few PT-specific EHR products that are CEHRT. To advance interoperability and exchange of standardized data, **it's expected that CMS will require PTs to participate in the PI category in the future.**
- **EHR software needs to promote broad connectivity across health care networks;** EHR software should support standards-based methods for secure and efficient exchange of patient information. **ONC's and CMS' rules require EHRs certified by ONC to implement the USCDI and HL7's Fast**

    Healthcare Information Resources specification (standard for exchanging health care information electronically) to support access, exchange, and use of EHI.
- The use of CEHRT also is required to participate in Advanced APMs. **Opportunities for Advanced APM participation (and eligibility to obtain a bonus payment) will continue to be limited** until PTs have CEHRT.

Financial and Administrative Implications

- **If you are a developer of certified health IT and do not adequately respond to a request for EHI, you may be accused of info blocking**, which has negative financial and administrative implications.

Recommendations

- **Be transparent with your clients** about the technology's ability to support exchange of EHI.
- **Explain to your clients how you will support them** in responding to requests for access, exchange, or use of EHI, and help them avoid engaging in info blocking.
- **Explore the ONC certification process.** Although there is a financial and administrative cost to certification, PTs will need to be able to share electronic clinical information in a standardized format in the future.
- **Recognize the implications for PTs who are not using CEHRT** so those PTs can maximize their opportunities to increase payment under federal payer programs.
- **Understand that when PT providers do not use CEHRT, it may lead to fewer referrals**.

Consequences of Noncompliance

The different categories of actors face different penalties and disincentives. Health IT developers, HINs, and HIEs are subject to civil monetary penalties of up to $1 million per violation. However, although the rule takes effect April 5, 2021, these penalties won't be enforced until HHS finalizes rules regarding them.

Health care providers will be subject to yet-to-be-defined "appropriate disincentives" for engaging in info blocking. What those "appropriate disincentives" will be and how they will be determined and assessed are subject to a future rulemaking.

Exceptions: Accepted Reasons for Restricting Information Access

Given the rule's broad definition of info blocking, Congress directed ONC to identify valid reasons to restrict information access. As a result, the rule includes eight exceptions to info blocking that can allow you to avoid penalties or disincentives. Five exceptions involve instances of not fulfilling requests, and three involve how requests are fulfilled.

If you believe you may meet one or more exceptions, proceed with caution — each exception has detailed requirements. That said, even if you fail to meet all conditions of an exception, you still may qualify. Your specific circumstances will be evaluated to determine whether the actions constituted info blocking. You should consult with an attorney familiar with these issues.

The Code of Federal Regulations citation next to each exception provides the full language of each for more detail.

Exceptions That Involve Not Fulfilling Requests for Access, Exchange, or Use of EHI

- **Preventing harm (**45 CFR 171.201**).** You may engage in practices that are reasonable and necessary to prevent harm to a patient or other person. The practice must be no broader than necessary to substantially reduce that risk. The practice must be consistent with a written organizational policy or based on a determination specific to the facts and circumstances.
- **Privacy (**45 CFR 171.202**).** You may deny an EHI request in order to protect the individual's privacy under one or more of four scenarios that recognize existing privacy laws and practices. You are not required to use or disclose EHI in a way that is prohibited under state or federal law.
- **Security (**45 CFR 171.203**).** You may engage in practices that protect the security of the EHI. The practice must be directly related to safeguarding the information's confidentiality, integrity, and availability; be tailored to the specific security risk being addressed; be nondiscriminatory; and not be onerous on those seeking access.
- **Infeasibility (**45 CFR 171.204**).** You may decline a request for EHI that is infeasible. For example, you may not have — and may be unable to obtain — the needed technological capabilities, legal rights, financial resources, or other means to comply to a particular request. Or you may be able to comply with the request but only by incurring an unreasonable cost or other burden. If you claim infeasibility, you must provide the requester with a written explanation of why the request was denied.
- **Health IT performance (**45 CFR 171.205**).**You may make health IT temporarily unavailable so that you can perform maintenance or improvements. This exception recognizes the need for health IT to perform properly and efficiently.

Exceptions That Involve Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

- **Content and manner (**45 CFR 171.301**).** If you are technically unable to or cannot reach agreeable terms about fulfilling a request in the manner requested, you must fulfill it in an alternative manner as soon as possible.
- **Fees (**45 CFR 171.302**).** You may set fees to recover reasonable costs, including a reasonable profit margin, for fulfilling EHI requests. These fees must be:
  - Based on objective and verifiable criteria that you apply uniformly to similar requests.
  - Relative to your costs, which can't include costs already recovered for the same request.
- **Licensing Exception (**45 CFR 171.303**).** It will not be information blocking for you to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met. This exception allows you to protect the value of your innovations and charge reasonable royalties in order to earn returns on investments you have made to develop, maintain, and update those innovations. The practice must meet these conditions:
  - You must begin license negotiations with the requestor within 10 business days from receipt of the request and negotiate a license within 30 business days from receipt of the request.
  - Conditions related to licensing:
    - Scope of rights.
    - Reasonable royalty.
    - Nondiscriminatory terms.
    - Collateral terms.
    - Nondisclosure agreement.
  - Additional conditions relating to the provision of interoperability elements.
  - If you charge a royalty for the use of interoperability elements, it must be reasonable and comply with certain requirements.
  - The terms (including royalty terms) on which you license and otherwise provide the interoperability elements must be nondiscriminatory and comply with certain requirements.

Appendix: Information Blocking Scenarios

The following are fictitious scenarios illustrating how the info blocking rule can and cannot be applied. Consult with an attorney familiar with these issues for guidance on your specific situation.

The attorney for a patient who recently received treatment at a hospital outpatient department requests medical records from the patient's most recent episode of care. The hospital does not respond within three days.

An individual's personal representative, such as an attorney, has the right to access protected health information (including ePHI) about the individual they represent. The hospital should take steps to verify the identity of the attorney, but if they deny or unreasonably delay a response, they can be accused of info blocking.

A front desk receptionist employed by a physical therapy private practice ignores a physician's request for EHI.

The physical therapy practice is subject to the info blocking regulations. The practice owner should know that ignoring a request for EHI is unreasonable and will interfere with the exchange and use of EHI, making the practice noncompliant.

A physical therapist in private practice treats a patient over 10 visits. Upon discharge, the patient is not provided with their EHI.

There is no requirement to proactively give EHI to patients or others who have not requested it.

A physical therapist in private practice receives a request from a former patient for their 2018 medical records. The PT isn't able to access the records immediately.

A patient can request EHI from previous years, and the provider still must respond promptly or be accused of info blocking. Although the HIPAA privacy rule allows up to 30 calendar days from receipt of the request to respond, if a provider can more promptly fulfill the request but doesn't, their actions could be considered info blocking.

A patient is discharged from a SNF to an outpatient physical therapy practice, which then requests the patient's medical record from the SNF. The SNF doesn't use an EHR that is certified under the ONC Health IT Certification Program and so technically is unable to provide the EHI in the manner requested.

The info blocking regulations don't require the use of any specific standard or functionality, but providers are expected to provide information in the manner requested. However, if the SNF is technically unable to fulfill the request, it must use an alternate manner agreed upon with the requester, based on an order of priority specified in the "Content and Manner" exception.

On Oct 7, 2022, a patient begins receiving home health services. Six weeks later she is discharged from home health and begins to receive outpatient physical therapy from a private practice. She requests her all her medical records from the home health agency, which maintains some of them in paper format only. The HHA is unsure if it only is required to provide the records it has maintained electronically.

The patient's home health care begins after Oct. 6, 2022, when fulfillment of requests for EHI expands beyond providing the limited USCDI data and must include any data required under designated HIPAA regulations. In this case, then, the HHA must provide both the records stored electronically and those saved on paper, since the patient asked for, and is entitled under HIPAA to receive, all of her records.

Therapy contract companies are not listed under the definition of "health care provider." A therapy contract company and its PT employees are unsure if they are exempt from the info blocking regulations.

A therapy contract company may not fall under the definition of "health care provider," but, their organization may be considered a health information network or exchange, which is an "actor" subject to info blocking rules. To determine whether their organization meets the definition of one of these entities, the therapy company administrator or compliance officer should look up the definition in the regulation 45 CFR 171.102 and review the easy-to-understand ONC Information Blocking Actors fact sheet definitions.

A physical therapist works for a therapy contract company that is determined to be health information network. The PT also works PRN for a few different SNFs. One of the therapist's patients is discharged from a SNF, and the patient's family member later requests the patient's physical therapy notes during the patient's SNF stay. The therapy contract company, the SNF, and the therapist are unsure who is responsible for responding to the request for EHI.

The physical therapist and the SNF both are subject to the regulations. The SNF is most likely to maintain and store the medical records, so the SNF should have policies and procedures on how to handle incoming requests for EHI from a patient or other legitimate requester. However, the PT employee also should be familiar with how requests for EHI are handled by both organizations.

A physical therapist in cash-based private practice does not fall under the HIPAA definition of covered entity. Not being a covered entity, the therapist ignores a patient's request for their medical records following an episode of care.

The therapist is subject to the penalties and disincentives associated with the info blocking rules. The regulations apply to health care providers, whether or not they are a HIPAA-covered entity or business associate.

Resources Used in This Advisory

- [HHS ONC Information Blocking Actors Fact Sheet](#)
- [Information Blocking Regulations (45 C.F.R Part 171)](#)
- [U.S. Core Data for Interoperability](#)
- [ONC Information Blocking Exceptions Fact Sheet](#)
- [HHS Individuals' Right Under HIPAA to Access their Health Information](#)
- [HHS ONC Information Blocking FAQs](#)
- [APTA Podcast: Understanding Information Blocking](#)

APTA Is Here to Help

APTA staff are ready to answer your questions about info blocking. Members can reach out to advocacy@apta.org with questions.

For more information on info blocking, check out these resources:

- [APTA Learning Center: Practical Application of Information Blocking and Interoperability Rules for the Physical Therapy Profession](#)
- [APTA Information Blocking Resources](#)
- [APTA Analysis: Complying with Information Blocking Rules](#)

See also: [Are You Hip to HIPAA?](#)

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Contact: advocacy@apta.org

Note: We will update this practice advisory as HHS releases additional guidance, including information on the penalties and disincentives.