

Information Blocking Overview Frequently Asked Questions

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Question	Answer
Do the rules apply to ACR members, such as radiologists?	Yes, HHS Information Blocking rules apply to three types of actors: providers, certain health IT developers, and networks/exchanges. This includes various physicians and non-physician professionals, among many other types of individuals and entities.
Do the rules require new technology purchases?	These specific rules do not mandate new product or service purchases. Providers may not always have the technological capability to fulfill requests for access, exchange, or use of electronic health information (EHI) in the manner requested. There may be other acceptable ways to facilitate requests pursuant to the technical capabilities of providers and requestors. Importantly, actors should familiarize themselves with all conditions of the exceptions. The "infeasibility" and "content/manner" exceptions are most relevant to this issue.
Are the rules limited to protecting patient-level access to EHI?	Patient-level access to EHI is one of several protected scenarios; however, the provision also applies to the full range of legally permissible access, exchange, or use of EHI by healthcare providers. Therefore, radiology providers can report when another provider, network, or vendor is impeding their EHI access, exchange, or use (for example, via unfair connectivity fees or ignored requests).
Do radiology providers need to give immediate access to reports before review by the referring physician?	HHS released a FAQ in March 2021 indicating that any organizational policy that delays release of EHI for any period of time to allow clinician review or to enable better communication with the patient would likely be an "interference." Importantly, "interferences" are not automatically rule violations. Rather, case-by-case HHS investigations of submitted complaints must determine whether violations occurred. For provider-actors specifically, the law requires that the provider knows the practice is both unreasonable and a likely interference.

How can radiology providers avoid surprising or confusing patients with unrequested data?

Some patients may prefer that radiology reports and other EHI conveying life-changing and/or complex observations be communicated by their referring provider rather than via an automated email, text message, or push notification to their phone.

Following communications with ACR and other stakeholders, HHS released two FAQs in 2022. First, HHS <u>clarified</u> that satisfying a patient's documented request to delay access would likely not be an interference (see link for details). Second, HHS <u>clarified</u> that providers could opt not to use texts, emails, and push notifications when EHI is initially made accessible (see link for details).

Do radiologists need to expedite imaging review and report creation?

The rules do not require expedited radiology turnaround times. Rather, the rules are about making EHI available when such data is finalized or otherwise used in medical decision-making.

Do the rules require patient-friendly translations of EHI?

Providing the patient with only a "patient-friendly" translation of EHI instead of appropriately responding in full to their request for access, exchange, and/or use of the EHI would likely be viewed by HHS as an interference. The rules do not prevent providers from voluntarily translating any EHI that patients have access to, but such translations cannot substitute for the requested EHI.

Can the exception for "preventing harm" be invoked for concerns about health literacy/confusion, misinformation, or mental health?

Not typically when a patient is requesting their EHI. For those scenarios, the exception <u>relies on the same types of harm</u> (i.e., physical harm) that serve as grounds for reviewable denial of an individual's right of access under the HIPAA Privacy Rule.

The applicable harm standard **changes** depending on the requestor.

What is Electronic
Health Information
(EHI), and does it
include radiology
images and other nonEHR, medical device
data?

The rules focus on sharing "EHI" as defined at 45 CFR § 171.102. As of a change on Oct. 6, 2022, the EHI definition includes essentially all electronic protected health information (ePHI) (see 45 CFR 160.103) that is part of the HIPAA designated record set (see 45 CFR § 164.501). Consequently, the current EHI definition is generally inclusive of non-deidentified medical images and other ePHI used by radiologists to make health care decisions about an individual.

Can providers also be networks or EHR developers under these rules? Yes. Certain providers may also meet one of the two non-provider actor definitions (i.e., developers of certified health IT or health information networks/exchanges). For example, a hospital that offers certain health IT to another provider would likely meet the developer-actor definition. These actor types have a slightly different statutory definition of "information blocking" and also have different penalties for violations that occur while acting in that capacity.

Are radiology IT vendors and imaging device manufacturers subject to the information blocking rules?

This depends on whether the entity in question meets one of the three actor definitions.

First, any entity that develops or offers health IT products certified under the ONC health IT certification program would meet the "Health IT Developer of Certified Health IT" actor definition. This type of actor would be subject to the rules across their full portfolio, even if the specific IT product at the root of an information blocking claim was not their certified product.

Additionally, vendors of radiology IT systems and/or imaging data exchange services would likely meet the "Health Information Network or Health Information Exchange" actor definition if they enable the exchange of EHI between two or more disparate individuals/entities for treatment, payment, or health care operations purposes.

What are the penalties/disincentives for information blocking violations?

The answer varies depending on the actor. Provider-actors found by HHS investigation to be in violation are subject to relevant "disincentives," which are generally related to Medicare quality incentive programs. HHS will also publish online information about confirmed violations.

Developer-actors and network/exchange-actors will be subject to up to \$1 million in civil monetary penalties (CMPs) per violation.

My practice has encountered possible information blocking by another actor. How do I report it?

Claims can be reported on the HHS' <u>information blocking portal</u> website. If preferred, claims can be reported anonymously. This <u>fact</u> <u>sheet</u> describes the reporting process.

Are all claims investigated? How are they prioritized?

HHS <u>anticipates</u> not being able to investigate all claims. Instead, HHS will prioritize investigations on claims that involve possible harms, negative impacts on patient care, occurred over a long duration, and/or caused financial loss to federal programs or others. For developers and networks/exchanges only, HHS will also prioritize when the actor has knowledge of the possible blocking—this knowledge is already required by law for provider-actors.

How do I find more information?

In general, the ACR recommends seeking first-party sources of information on the rules, as the information blocking paradigm is complex and involves multiple HHS offices, agencies, and rule updates. The relevant primary HHS webpage is here.