Information Blocking Overview – ACR.org Frequently Asked Questions

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Do radiologists, interventional radiologists, nuclear medicine physicians, and radiation oncologists meet the information blocking provision's "provider" actor definition?

Yes, the <u>provider</u> definition includes physicians and non-physician-practitioners, among many other types of individuals and entities. Please see this <u>HHS guidance</u> for more information.

Are radiology providers required to purchase new technologies or services for compliance?

The information blocking provision does not mandate new technology purchases. Radiology providers may not always have the technological capabilities to satisfy certain requests for access, exchange, or use of electronic health information (EHI) in the manner requested. There may be other acceptable ways to facilitate access depending on the capabilities of providers and requestors.

Actors should familiarize themselves with all conditions of the <u>eight exceptions</u>—the "infeasibility" and "content/manner" exceptions are most relevant to this issue. The "content/manner" exception essentially provides a checklist for how to appropriately respond to legally permissible requests for EHI.

Is the information blocking provision limited to patient-level communication?

No. Provider-to-patient EHI sharing is one of several applicable exchange scenarios. The provision also applies to the full range of *legally permissible* access, exchange, or use of EHI. This is typically inclusive of provider-to-provider exchange as well.

The following is a noncomprehensive list of radiology-relevant examples not involving patient-level access that would implicate the provision and likely be subject to case-by-case HHS investigations:

- A hospital fails to appropriately respond to an unaffiliated radiology practice seeking to exchange a shared patient's EHI with the referring physician who uses that hospital's IT systems.
- A vendor of certified EHR software charges a radiology practice unreasonable fees to enable exchange of EHI between end-users of their EHR and the radiology practice.
- A health information network fails to appropriately respond to a request for exchange of EHI between a radiology provider using their exchange services and another provider using a competitor network's exchange services.

Do radiology providers need to provide patients with unrequested access to radiology reports before review by the referring physician?

HHS released a FAQ in March 2021 suggesting 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. Moreover, the notion of a "request" described in the FAQ appears to be broadly inclusive of background activities that are typically nontransparent to providers, such as portal logins and personal health app queries. HHS also clarified in subsequent public discussions that interferences do not always involve requests—for example, broad policies that result downstream in unnecessary delays or impediments to EHI access could be viewed by HHS as interference.

Critically, an "interference" does not automatically mean information blocking occurred. Rather, <u>case-by-case HHS investigations</u> of submitted information blocking complaints determine whether violations occurred. For provider-actors specifically, the information blocking definition in the law requires that the provider knows the practice is both unreasonable *and* a likely interference.

How can imaging providers avoid surprising their patients with unrequested radiology reports?

HHS is aware of physicians' concerns with surprising a patient with an unrequested radiology report—or other EHI not specifically requested by that patient—that may convey life-ending, life-changing, or complex clinical findings ideally conveyed by a physician who is available and ready to answer follow-up questions. Following extensive communications from ACR and other stakeholders, HHS released two FAQs relevant to this issue:

- HHS clarified in a Feb. 2022 FAQ that satisfying a patient's request to delay access would likely
 not be an interference. This would likely involve documenting the patient's preference in
 advance, for example via a patient form question. Importantly, the patient and provider must
 agree on the timeframe or conditions for the delay, the timeframe or conditions must have been
 met, and there must be no extended or unnecessary delays in meeting the documented
 timeframe or conditions.
- Additionally, HHS clarified in a separate Feb. 2022 <u>FAQ</u> that providers could choose to not notify their patients of EHI accessibility (e.g., via email or text). Stopping notifications would allow data to be accessible to patients seeking it without surprising or confusing others.

If planning to implement either of these approaches, radiology providers must carefully review HHS' two Feb. 2022 FAQs linked above with appropriate legal/compliance teams.

Do radiologists need to expedite their image review and report creation workflow?

A January 2021 HHS FAQ clarified that data is effectively sharable "EHI" when it is used to make health care decisions about an individual. This would generally exclude unfinalized radiology reports-in-progress unless an unsigned report is being used for decision-making about an individual. HHS does not require radiology report creation or subsequent use in decision-making to be expedited.

Would patient-level summaries of EHI, such as translations of radiology reports for patient audiences, suffice?

Generally, no. Providing the patient with only a patient-friendly translation of their report instead of appropriately responding to their request for access, exchange, and/or use of the EHI would likely be viewed by HHS as an interference. The provision does not forbid or require providing patient-friendly summaries of EHI *in addition to* providing the EHI requested by the patient, but it cannot be provided *instead of* the requested EHI.

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

Generally, not when a patient is requesting their own EHI. For those scenarios, the substantial harm standard required for this exception essentially relies on the <u>same types of physical harm</u> that serve as grounds for reviewable denial of an individual's right of access under the HIPAA Privacy Rule. This would exclude concerns about humane communication of findings, mental health problems, confusion about complex clinical terminology, extreme patient anxiety about a finding, or even the threat of misinformed decision-making. This exception would also require an individualized determination by the provider—it could not be applied universally by policy.

Note that when dealing with non-patient requests for EHI, the harm standard may be reduced depending on the requestor. Please see HHS' related FAQ for details.

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

The information blocking provision focuses on sharing "EHI" as defined at 45 CFR § 171.102. For the first 18 months of the program only, the EHI definition was limited to data represented by the U.S. Core Data for Interoperability (USCDI) Version 1, which included the "imaging narrative" data element. Images and other data types excluded from USCDI Version 1 were not EHI during this temporary period. This limitation is no longer relevant as of Oct. 6, 2022.

Beginning 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 expanded EHI definition is generally inclusive of non-deidentified medical images used by radiologists to make health care decisions about an individual, among many other data types not included in the EHI definition prior to Oct. 6, 2022. To simplify, if a patient has a right to request the ePHI under HIPAA Right of Access, it is likely "EHI."

The "expanded" EHI definition could include various data types that are not necessarily thought of as being accessible to non-provider audiences, such as AI algorithm output data containing ePHI. Therefore, it is generally advisable that radiology practices work with qualified legal counsel to understand what patient data they keep that is technically EHI, in addition to understanding the requirements of the <u>eight exceptions</u>.

Is information blocking limited to electronic health record (EHR) technology, EHR vendors/users, and instances involving specifically EHR-curated data?

No. The type of health IT system used by the provider is generally irrelevant to the rule. The technology is only relevant to the in-house capabilities of the provider to share EHI in response to legally permissible

requests (please see the "content/manner" and "infeasibility" exceptions for more details). EHI can be stored in or transmitted by medical devices and information technology solutions other than traditional EHR-type software.

Can provider actors simultaneously meet one of the other two actor definitions?

Yes. Certain providers may also meet one of the two non-provider <u>actor definitions</u> (i.e., developer of certified health IT or health information network/exchange). These actor types have a slightly different definition of information blocking in the law and will have different penalties for information blocking violations that occur while acting in that capacity.

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

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 information blocking rules across their full product portfolio, even if the specific IT product at the root of an information blocking claim was not certified.

Additionally, several vendors of radiology IT systems and/or radiology 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 actors?

Penalties/disincentives vary according to the type of actor. *Providers* will be subject to as-of-yet-unidentified "disincentives" under HHS' existing authorities. These disincentives must be established via a future HHS rulemaking. It is currently unclear if providers will be penalized for claims in the gap between April 5, 2021, and whenever the future disincentives rule is promulgated, though HHS claims they have the statutory ability to do so.

Developers and networks/exchanges will be subject to up to \$1 million in civil monetary penalties (CMPs) per violation.

HHS officials are informally referring to the information blocking provision as "information sharing" requirements? What is the difference?

No difference—both reference the same regulatory paradigm.

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

Claims can be reported on the HHS' <u>information blocking portal</u> website. HHS has been collecting information blocking complaints since 2021 (see this <u>FAQ</u>). The agency <u>recently released</u> high-level claims summary data.

Where can I find more information?

HHS is the authoritative source of information on the information blocking rules. However, the ACR offers educational resources, including links to pertinent HHS documents, via ACR's Information Blocking resource webpage.