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

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

The information blocking provision does not require 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). Actors should familiarize themselves with all conditions of the eight exceptions—the infeasibility and content/manner exceptions are pertinent to this question.

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

Provider-to-patient EHI sharing is one of several applicable exchange scenarios. The provision also applies to a wide range of legally permissible access, exchange, or use of EHI, including provider-to-provider and vendor-to-provider exchange.

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

- A hospital fails to appropriately respond to an unaffiliated radiology practice seeking to exchange EHI with a 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 (e.g., via patient portals or personal health applications) before review by the referring physician?

According to an HHS FAQ published in January 2021, providers are not required to proactively provide EHI to those who have not requested it. However, according to an HHS FAQ published in March 2021, 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 latter FAQ appears to be broadly inclusive of background activities that are typically nontransparent to providers, such as portal logins and personal health app queries. It is unclear how HHS believes providers can avoid brief delays if they wait for a request before enabling access.

Critically, *an "interference" does not automatically mean information blocking occurred*. Rather, case-by-case HHS investigations 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 unreasonable *and* a likely interference. It is unknown how HHS intends to investigate and enforce practices understood by the provider to be medically, professionally, and ethically reasonable.

How does HHS recommend imaging providers responsibly 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 data not specifically requested by that patient, that may convey life-ending, life-changing, or complex clinical findings. However, HHS has not released official compliance guidance to resolve this concern.

Note that an HHS official made an interesting verbal statement at 54:53 of a Sep. 14, 2021, HHS webinar on information blocking. To briefly summarize, the HHS official indicated that "the most success they have seen" is when patients are engaged and asked (for example, during order entry) whether they want results data early, or if they want to wait for contact from the referring physician/care team.

The ACR subsequently asked for HHS confirmation that the Sep. 14, 2021, webinar statement represented a legitimate regulatory compliance approach to avoid unrequested, surprise reports, and if HHS plans to produce template form language for providers to acceptably ask this question during order entry or patient check-in. As of this writing, HHS has yet to provide additional clarification.

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

A January 2021 HHS FAQ clarified that data is effectively sharable EHI beginning 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.

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 creating patient-friendly summaries of EHI and sending those *in addition to* responding to the patient's actual request.

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

Generally, no. The substantial harm standard required for this exception essentially relies on the same types of physical harm 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 broadly.

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*, the EHI definition will be limited to data represented by the U.S. Core Data for Interoperability (USCDI) Version 1, which includes the "imaging narrative" data element. Images and other data types excluded from USCDI Version 1 are not EHI during this temporary period.

However, *beginning Oct. 6, 2022*, the EHI definition will effectively expand to include 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, that expanded EHI definition will generally be inclusive of non-deidentified medical images used by radiologists to make health care decisions about an individual, among many other data types not currently included in the temporary EHI definition. To simplify, if a patient has a right to request the ePHI under HIPAA Right of Access, it is typically "EHI."

The expanded EHI definition would also include various other types of non-EHR data that meet the above definition, such as certain imaging AI outputs used by a radiologist for health care decision-making about an individual. Therefore, it is generally advisable that radiology practices understand what types of patient data they have that will be subject to the provision on Oct. 6, 2022, in addition to understanding the requirements of the eight exceptions.

The imaging portions of the USCDI standard changed significantly between Versions 1 and 2. Does this alter the information blocking paradigm?

No. Changes to the USCDI standard are not expected to have a practical impact on the information blocking provision. Version 1 of the USCDI was incorporated by reference into the regulatory definition of EHI—updating to a later version of the standard would require rulemaking. However, concerns regarding use of an outdated standard will become moot in Oct. 2022 when the EHI definition will no longer reference the USCDI standard and will instead reference HIPAA definitions.

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, particularly for providers and health information networks/exchanges. The provision revolves around EHI sharing, which can be

stored in or transmitted by medical devices and other information technology solutions beyond 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 actor definitions (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 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. Essentially, any entity that develops or offers an active certified product listed on ONC's Certified Health IT Product List would meet this definition.

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. Perhaps counterintuitively, this definition is not limited to traditional regional health information exchanges. Several radiology IT vendors and other entities that do not currently meet this actor definition in 2021—for example, those that enable sharing of imaging ePHI between unaffiliated providers—will likely meet this actor definition after the EHI definition expands on Oct. 6, 2022.

What are the penalties/disincentives for information blocking actors?

Penalties/disincentives vary depending on the actor type. *Providers* will be subject to as-of-yet-unidentified "disincentives" under HHS' existing authorities. These disincentives must be established via a future HHS rulemaking. There is currently no estimated timeframe for that future rulemaking.

Developers and networks/exchanges will be subject to up to $1 million in civil monetary penalties (CMPs) per violation. The CMPs rule was proposed in 2020 has not yet been finalized as of this writing. HHS officials stated publicly that the CMPs final rule may be published by the end of 2021, although this estimate is subject to change.

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

No difference—both reference the same requirements.

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

Information blocking complaints are currently being collected by HHS (see this FAQ). However, it is unclear if providers will be penalized for actions that occur in the gap between April 5, 2021, and whenever the disincentives rule is finalized in the future. Enforcement discretion is being used by HHS for the two industry actor types until finalization of the CMPs. The effect of the missing HHS enforcement rules on reporting is unknown, as HHS has not released data about complaints or outcomes.

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.