The American College of Radiology provides the following only as general information. Readers should not construe this educational resource to provide specific legal advice on their individual practice matters. This information is subject to change depending on future rules and/or clarifications.

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 of any kind. 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 the conditions of the eight exceptions—the infeasibility and content/manner exceptions are especially relevant to this question.

Is the information blocking provision primarily focused on patient-level access?
Provider-to-patient sharing is one of many relevant scenarios. The provision applies to the full range of legally permissible access, exchange, or use of EHI, including provider-to-provider and vendor-to-provider scenarios.

Congress intended for the information blocking provision to deter unreasonable barriers to exchange, particularly anticompetitive business practices by providers, vendors, and networks. It is generally anticipated that many reports to HHS investigators of information blocking in the future will be situations in which providers were delayed or denied access to EHI by competitors.

Do radiology providers need to provide patients with immediate access to radiology reports on patient portals?
According to an HHS FAQ clarification (see Interference subsection) on March 19, 2021, any organizational policy that delays release of EHI for any period of time to allow clinician review of the EHI or to enable better communication with the patient would be a “likely interference.” Note that this clarification appears to contradict an earlier Jan. 15, 2021 FAQ which indicated there is no requirement to proactively make available any EHI to patients or others who have not requested it. While proactively facilitating unrequested access to EHI is not technically required per the Jan. 15 FAQ, it is essentially suggested by the March 19 FAQ.

Critically, a “likely interference” by a provider does not automatically mean information blocking occurred. The statutory definition of information blocking by providers also requires that the provider knows the practice in question is “unreasonable.” In lieu of enforcement rules and relevant guidance, there continues to be ambiguity about what it means for a provider to know that the practice in
question is unreasonable. This consideration is particularly relevant for situations in which an HHS-defined likely interference is viewed by physicians to be medically, professionally, and/or ethically reasonable.

Finally, note that portals are not a mandatory mechanism for providing access, exchange, and use of EHI. The content/manner exception is most relevant to this component of the question and should be carefully reviewed. Insisting that a patient only access, exchange, or use EHI from the provider’s patient portal instead of in the manner requested by the patient could implicate the provision. For example, if the patient authorized a third-party mobile app for accessing EHI, and the data was not available in that app upon request, this would likely constitute an interference per the March 19, 2021 clarification.

**Does the March 19, 2021 clarification mean radiologists must expedite review and reporting?**
Generally, no. A January 15, 2021 HHS FAQ indicated that in-progress, unfinalized data would only be sharable EHI beginning when it is being used to make health care decisions about an individual.

**Would patient-level summaries of EHI, such as translations of radiology reports for patients, suffice?**
Generally, no. Providing the patient with only a summary of their EHI (such as a translated, patient-friendly summary of findings) instead of appropriately responding to the request for access, exchange, and/or use of EHI would likely implicate the provision. The provision does not forbid (nor require) providing patient-friendly summaries of EHI *in addition* to the requested EHI.

As mentioned previously, if the provider is focused on portal-enabled access as the only mechanism of access, the provision could be implicated if the patient requested the EHI via some other means (for example, a third-party mobile app). Additionally, portal-enabled formats may or may not limit the recipient’s desired use of the EHI. Therefore, actors should understand the conditions of the eight exceptions—particularly the exceptions for infeasibility and content/manner—to respond to requests appropriately, even if they believe they are covered by exceptionally robust technological approaches to sharing EHI.

**Will the EHI definition eventually include images?**
Any ePHI that is part of the HIPAA designated record set, with limited exceptions unrelated to this question, would meet the EHI definition beginning in Oct. 2022. This will generally include medical images as well as any device output data that is ePHI and part of the designated record set.

**Can provider actors also meet one (or more) of the other actor definitions?**
Generally, yes. Some providers may 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 different statutory definition of “information blocking” and will have different penalties.

**Can the HHS-defined exception for preventing harm be used with respect to ethical concerns around patient confusion, Internet-misinformed care decisions, and mental health?**
Generally, no. The substantial harm standard required for this exception essentially relies on the same types of harm that serve as grounds for reviewable denial of an individual’s right of access under the
HIPAA Privacy Rule. It also requires an individualized determination (i.e., cannot be applied by organizational policy), which can be difficult to assess in radiology practice settings.

If, for example, a patient or the patient’s referring provider specifically indicated that a particular finding could lead to the patient physically harming themself or someone else, and all conditions of the exception were met, the preventing harm exception could be used. However, the exception could not be used for scenarios in which individualized determinations were not made, or if the harm concerns were limited to mental health problems, confusion, anxiety, or broad concerns of misinformed care decision-making.

Are radiology health IT vendors and medical device manufacturers subject to the information blocking provision?
Any entity that develops or offers health IT products certified under the ONC health IT certification program could potentially meet the “developer of certified health IT” actor definition. If so, that entity would be subject to the information blocking rules across their full portfolio, even if the product at the root of the information blocking claim was not itself ONC-certified. Developers of certified products are searchable on ONC’s Certified Health IT Product List.

It is also conceivable that vendors of radiology IT systems or services could meet the health information network/exchange actor definition. See the HHS document on actor definitions.

My practice has encountered information blocking by another actor. How do I report it?
While information blocking complaints are currently being collected by HHS here, it is unclear how these reported complaints are being used without the availability of enforcement rules to guide regulatory investigations and levying of disincentives.