

Enforcement of information blocking regulation: What this means for physicians

On June 27, 2023, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) finalized the regulations around civil money penalties (CMP) for [information blocking](#) enforcement from the [21st Century Cures Act \(Cures Act\)](#). **Enforcement begins Sept. 1, 2023.**

The Cures Act authorizes CMPs of up to \$1 million per violation for any practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of [electronic health information \(EHI\)](#) if the practice is conducted by an entity that is: a developer of certified health information technology (health IT) offering certified health IT, e.g., electronic health record (EHR) developer; a health information exchange (HIE); or a health information network (HIN). These entities are considered “actors” under this regulation.

In instances where physicians believe an EHR developer or HIE/HIN is blocking information unnecessarily or using legal or financial roadblocks to prevent access to patients’ medical records, those actors may be information blockers and subject to CMPs.

The following are specific areas of focus and themes OIG will consider during investigations or enforcement. Physicians should take these into consideration if they believe an EHR developer or HIE/HIN is blocking information.

To report complaints about information blocking, please visit the [ONC Information Blocking Portal](#) or the [OIG Hotline](#).

- **Intent is needed**

OIG has authority to seek CMPs for information blocking against actors who had a requisite intent to not broadly share EHI. OIG states that it will likely prioritize cases in which an actor has actual knowledge its practice was likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI.

- **Enforcement priorities**

OIG’s enforcement priorities will focus on information blocking that has resulted in, is causing, or had the potential to cause patient harm; significantly impacted a provider’s ability to care for patients; was of long duration; caused financial loss to federal health care programs, or other government or private entities; or was performed with actual knowledge. OIG emphasized that enforcement priorities will evolve as the agency gains more experience with these investigations. In addition, OIG can and does expect to investigate allegations of other information blocking conduct not covered by the priorities.

- **Volume of claims against an actor may factor into whether or not OIG will investigate**

OIG may evaluate allegations and prioritize investigations based in part on the volume of claims relating to the same (or similar) conduct by the same actor.

- **OIG can refer information collected from investigations to other agencies, including OCR and CMS**

In the course of its information blocking investigations, OIG may refer certain cases related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to the HHS Office for Civil Rights (OCR) to resolve these claims or contribute to an investigation over possible HIPAA violations. Also, if OIG’s information blocking investigation suggests an actor may be out of compliance with Centers for Medicare & Medicaid Services (CMS) programmatic requirements,

OIG may refer such matters to CMS.

- **Six-year time limit**

OIG has six years from the date an actor committed a practice that constitutes information blocking to impose a CMP.

- **No retroactive look-back before Sept. 1 for potential claims**

Information blocking enforcement begins Sept. 1, 2023. OIG states that it will not impose a CMP on information blocking conduct occurring before that date.

- **Appeals will be heard**

Actors will have the opportunity to appeal CMPs through an administrative law judge. It is important to note that actors in a CMP enforcement action bear the burden of proof for affirmative defenses and mitigating circumstances by a preponderance of the evidence.

- **Self-disclosure is an option to lower penalties**

OIG will issue the procedures around a self-disclosure protocol to resolve CMP liability and allow for lower penalties. As the agency gains more experience investigating and imposing CMPs for information blocking, it may further consider alternative enforcement approaches.

How could this enforcement regulation and future related proposals impact physicians?

Providers (e.g., physicians and hospitals) are not subject to CMPs, unless there are specific circumstances when they could also be considered a health IT developer or an HIE/HIN. However, the Cures Act also authorizes “appropriate disincentives” for health care providers that are deemed information blockers. The Office of the National Coordinator for Health Information Technology (ONC) and OIG are working on a separate regulatory process for health care provider disincentives. ONC intends to publish a proposed regulation on provider disincentives in fall of 2023.

As we gear up for the physician and provider disincentive regulatory process, the American Medical Association is seeking clarification on steps that a physician should consider if their EHR’s developer is subject to an information blocking CMP. For instance, further information is needed to advise physicians on the potential ramifications of meeting CMS program requirements if their EHR developer is subject to a CMP and the EHR is decertified by the federal government.

Even though OIG’s recent CMP regulation focuses on non-physician actors, this information could be helpful to physicians as they evaluate their ongoing compliance with information blocking. The AMA expects the OIG and ONC to incorporate several of these themes in future regulation. However, this information should not be considered legal advice. The AMA recommends physicians seek legal counsel to ensure compliance with all regulations.

Key difference between this regulation and any physician-related enforcement action

It is also important to note that the Cures Act established two different knowledge standards for actors’ practices within the statute’s definition of information blocking. For health IT developers, as well as HIEs/HINs, the standard is whether they know, or should have known, that a practice is likely to interfere with the access, exchange, or use of EHI. For health care providers (physicians, hospitals, etc.), the standard is whether they **know that the practice is unreasonable** and is likely to interfere with the access, exchange, or use of EHI.

References

[OIG Information Blocking webpage](#)

[ONC Information Blocking resources](#)

AMA News: [What is information blocking? How do I comply with info blocking and where do I start? What is EHI?](#)