

Information blocking disincentives

Overview

The 21st Century Cures Act directed the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to investigate information blocking claims and assess civil monetary penalties (CMPs) of up to \$1,252,992 per violation for health IT developers, e.g., electronic health record (EHR) developers, health information networks (HIN), and health information exchanges (HIE). The OIG incorporated information blocking regulations into its CMP regulations, establishing a broad definition of "information blocking" as any practice likely to interfere with access, exchange, or use of electronic health information (EHI), unless covered by an exception. The definition of information blocking differs for providers compared to EHR developers, HINs, and HIEs—providers must "know" that a practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI, whereas developers, HINs, and HIEs "know, or should know" that such a practice is unreasonable or likely to cause interference with access, exchange, or use.

CMPs have only been in effect for EHR developers, HINs, and HIEs. Health care providers (e.g., hospitals, physicians, and Accountable Care Organizations) have been excluded from penalties and disincentives thus far. Health IT developers, HINs, HIEs, and providers are collectively known as "actors." On June 24, 2024, CMS and ONC released a Final Rule, implementing disincentives for health care providers participating in specific Medicare programs. These disincentives apply to Medicare-enrolled providers found to have committed information blocking, but do not extend to all health care providers. Hospitals and critical access hospitals (CAHs) face disincentives through the Medicare Promoting Interoperability (PI) Program, such as losing their status as meaningful EHR users and receiving reduced payment adjustments. Similarly, physicians participating in the Meritbased Incentive Payment System (MIPS) will receive a zero score for the Promoting Interoperability performance category if found guilty of information blocking.

For the Medicare Shared Savings Program (MSSP), health care providers, including Accountable Care Organizations (ACOs), may be barred from participation for at least one year if found to have committed information blocking. In this final rule, CMS offers MSSP participants more discretion and will consider the nature of the violation, the provider's efforts to correct the issue, and other relevant factors before applying disincentives.

The rule also includes a transparency requirement, mandating that information about provider actors determined to have committed information blocking be publicly posted on ONC's website. This includes the provider's name, address, the nature of the information blocking practice, and the applied disincentive.

Providers will be subject to CMS and ONC's disincentive regulations starting July 31, 2024.

Summary of CMS disincentives

If OIG refers an information blocking determination to CMS for agency action, CMS will apply disincentives to the following providers:

• For an eligible hospital, the eligible hospital's payment will be reduced by three quarters of the applicable percentage increase in the market basket update or rate-of-increase for hospitals; and

- For an eligible CAH, the CAH will be paid 100 percent of its reasonable costs instead of 101 percent of reasonable costs.
- A MIPS eligible clinician will not be a meaningful EHR user in a performance period if OIG refers a
 determination that the MIPS eligible clinician committed information blocking at any time during the calendar
 year of the performance period. This will result in a zero score for the PI performance category for that
 performance period. CMS notes that the applicable MIPS payment year is two calendar years after the
 performance period. For example, if OIG referred an information blocking determination in 2025, the
 disincentive would apply to the 2027 MIPS payment year.
- For ACOs, ACO participants, and ACO providers/suppliers, CMS may deny the addition of a health care provider to an ACO's participation list for a period of at least 1 year and may deny an ACO's application to participate in the MSSP for a period of at least 1 year. If the ACO were to reapply, CMS would then check for subsequent information blocking violations and for evidence of corrective action. For an existing ACO participant, CMS may notify the ACO that an ACO participant or an ACO provider/supplier has committed information blocking, so that the ACO can remove them from its ACO participant list or ACO provider/supplier list.

Groups and virtual groups

Groups are subject to MIPS payment adjustments based on their collective performance. If MIPS PI data is submitted as a group or virtual group, disincentives will be applied at that level. MIPS eligible clinicians submitting data both individually and as part of a group will be evaluated in both capacities, with the highest final score determining the payment adjustment.

For those with a taxpayer identification number (TIN) or national provider identifier (NPI) linked to a virtual group final score, CMS will use this score for the MIPS payment adjustment. If no virtual group score exists, CMS will use the highest available score.

When OIG refers an information blocking case involving multiple NPIs, disincentives will be applied to each NPI. If a group is found to have committed information blocking, disincentives will be applied at the group level. If an individual clinician within a group is responsible, CMS will target the disincentive to that individual clinician, not the group.

Reweighting policies and appeals

If a MIPS eligible clinician's PI performance category is reweighted to zero (e.g., if a physician is not patient facing or is in a practice of 15 or fewer eligible clinicians), the application of a disincentive will not affect the clinician's final score, and therefore that physician will not receive a CMS disincentive. If physicians choose to submit data for the PI performance category, their reweighting is canceled, and they could be subject to a disincentive.

CMS states that the ability to administratively appeal a disincentive depends on the authority used by CMS to establish the disincentive within the applicable CMS program. For example, if a physician is determined to have committed information blocking at any time during the calendar year of their PI performance, their PI performance category will result in a zero score—potentially impacting their overall MIPS performance. To file an appeal, that physician would then need to follow the established MIPS appeal process (also called a targeted review) to combat CMS' PI zero score disincentive. Currently, there is no meaningful opportunity for providers to appeal an OIG determination and only a limited appeal process for CMS disincentives.

The AMA had aggressively advocated to the Biden Administration of the need for the option of a corrective action plan, in addition to a more meaningful appeals process. We will continue to press these points with the Administration.

OIG investigation and enforcement priorities

An OIG investigation will depend on the specific facts and circumstances presented in the allegation, and the scope of an investigation (including individuals or entities involved) may change after it has begun. Most of the material and evidence will come from the provider actor whose conduct is at issue, and the OIG must assess whether the conduct constitutes information blocking. OIG may also refer the investigation to other federal agencies, e.g., the HHS Office for Civil Rights, which administers and enforces the Health Insurance Portability and Accountability Act (HIPAA) regulations. OIG will begin investigating allegations of information blocking against health care providers for conduct that occurs on or after **July 31, 2024.** OIG will exercise enforcement discretion not to make any information blocking determinations for actions occurring before that effective date.

OIG's priorities in investigating allegations of information blocking will be prioritized to focus on practices that (i) resulted in, are causing, or have the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) were of long duration; and (iv) caused financial loss to federal health care programs, or other government or private entities. Each individual allegation will be assessed to determine whether it implicates one or more of the enforcement priorities, or otherwise merits further investigation and potential enforcement action. OIG will subpoen a provider for information and documentation related to the allegation. Each allegation will be assessed on a case-by-case basis.

As discussed, the information blocking rules also regulate EHR developers, HINs, and HIEs, prohibiting them from blocking EHI. As in the case of physicians, EHR developers, HINs, and HIEs must comply with these regulations. Information blocking not only affects patients, but also physicians. Reach out to your EHR developer, HIN, or HIE to discuss what they are doing to come into compliance with CMS and ONC's regulations. The federal government has <u>created a process</u> and <u>a website</u> where you can file information blocking allegations regarding your EHR developer, HIN, HIE, or another health care entity covered by the rule.

Planning for and preventing disincentives

- Review policies and procedures: Ensure your policies, procedures, and practices regarding the access, exchange, or use of EHI comply with ONC's information blocking regulations and related laws (e.g., HIPAA and state laws). Develop policies and procedures outlining when and how you or your organization will apply information blocking exceptions.
- Update documentation: Review, update, or create documents that describe your commitment to sharing EHI.
- Train personnel:
 - Train information technology or administrative staff responsible for negotiating and implementing collaborations, partnerships, and other arrangements with third parties to prevent information blocking.
 - Train personnel responsible for implementing EHR interfaces and other interoperability elements on interoperability expectations, ONC's information blocking regulations, and OIG's enforcement priorities.
- Refine processes: Improve processes to create and retain records and other documents demonstrating
 compliance with ONC's information blocking regulations, including relevant exceptions. Consider
 documenting your use of information blocking exceptions within your EHR (e.g., in an office note).
- Identify counsel: Identify and retain counsel to help prepare for an OIG investigation.

The AMA has created several information blocking resources to assist in planning for and complying with the regulation:

- What is information blocking?
- How do I comply and where do I start?
- What is EHI?
- Summary of OIG regulations

HHS information blocking resources:

- Information blocking
- Disincentive common questions