PUBLICATION

Information Blocking: Disincentives Established for Health Care Providers

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July 01, 2024

The United States Department of Health and Human Services (HHS) has now established disincentives for certain health care providers if found by the Office of Inspector General (OIG) to have committed information blocking under the 21st Century Cures Act (Cures Act). In June 2023, the OIG published a Final Rule establishing penalties for information blocking actors other than health care providers. On June 24, 2024, HHS finalized the Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Rule (Disincentives Final Rule), which is one of several announced rules to establish disincentives for health care providers found to be information blocking. Information blocking is defined for health care providers as knowingly engaging in practices that are unreasonable and are likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information (EHI), except as required by law or covered by a regulatory exception.

Background:

In 2016, the Cures Act established the statutory provisions that penalize information blocking, pursuant to which health care providers and other actors (as defined by the law) could be held liable, while also authorizing HHS to identify "reasonable and necessary activities that do not constitute information blocking." In 2020, the Office of the National Coordinator for Health Information Technology (ONC) implemented certain provisions of the Cures Act, including information blocking regulations and regulatory exceptions for practices that do not constitute information blocking. While the OIG established penalties for actors other than health care providers last year, disincentives for health care providers have only just been finalized.

Disincentives Final Rule:

While HHS is seeking public input to establish disincentives for all health care providers subject to the information blocking regulations, this Disincentives Final Rule established disincentives applicable to only a subset of health care providers; those providers that are also Medicare-enrolled providers or suppliers. The Disincentives Final Rule included the following three disincentives aimed to deter information blocking by health care providers participating in various Medicare programs:

- 1. The Medicare Promoting Interoperability Program Disincentive finalizes that those eligible hospitals or critical access hospitals (CAH) found to have committed information blocking will not be considered meaningful electronic health record (EHR) users during the calendar year of the EHR reporting period when OIG refers its determination to the Centers for Medicare & Medicaid Services (CMS). This can significantly impact such health care providers' eligibility for financial incentives, reducing the annual market basket by three quarters for eligible hospitals and adjusting payment calculations for CAHs (i.e., payment will be reduced to 100 percent or reasonable costs instead of 101 percent). Regardless of whether multiple information blocking violations were identified as part of OIG's determination, including over multiple years, each referral of an information blocking determination by OIG will only affect an eligible hospital's or CAH's status as a meaningful EHR user in a single EHR reporting period;
- 2. The Quality Payment Program Disincentive finalizes that under the Merit-based Incentive Payment System (MIPS), eligible clinicians (including group practices) found to have committed information blocking will not be

recognized as meaningful EHR users for the calendar year of the performance period when OIG refers its determination to CMS. This results in a zero score in the MIPS Promoting Interoperability performance category, affecting health care providers' overall MIPS score and financial reimbursements. CMS has modified its policy to clarify that only the individual who has committed information blocking will be subject to a disincentive even if the individual reports as part of a group modifying the proposed rule policy. Regardless of whether multiple information blocking violations were identified as part of OIG's determination, including over multiple years, each referral of an information blocking determination by OIG will only affect a MIPS eligible clinician's status as a meaningful EHR user in a single EHR reporting period; and

3. The Medicare Shared Savings Program (Shared Savings Program) Disincentive finalizes that participants in the Medicare Shared Savings Program, including Accountable Care Organizations (ACOs), ACO participants, or ACO providers or suppliers, found to have committed information blocking may be ineligible to participate in the program for at least one year, resulting in a loss of potential shared savings revenue. For an ACO applicant who is a health care provider, CMS may deny the ACO's application to participate in the shared savings program for the upcoming performance year. For ACOs already participating in the Shared Savings Program, CMS may terminate the ACO's participation agreement. Before applying this disincentive, CMS will consider various factors, such as the time since the information blocking occurred and whether the health care provider has taken steps to correct the problem. CMS will, however, determine if it would be appropriate for the period to exceed one year if OIG has made any subsequent determinations of information blocking.

OIG may begin investigating health care provider actors soon after the effective date of the Disincentives Final Rule, which will be 30 days after the rule is published in the Federal Register. Importantly, the OIG will exercise enforcement discretion and review each allegation on a case-by-case basis. When a disincentive is imposed, the appropriate agency will notify the health care provider using usual methods of communication, indicating that the referral is made pursuant to the statutory requirement. As part of the referral, OIG stated it will provide information to explain its determination, which may include:

- 1. The dates when OIG has determined the information blocking violation(s) occurred;
- 2. Analysis to explain how the evidence demonstrates the health care provider committed information blocking (for instance, that the health care provider's "practice" meets each element of the information blocking definition);
- 3. Copies of transcripts and video recordings (if applicable) of any witness and affected party testimony;
- 4. Copies of evidence collected during the investigation (regardless of whether it was collected by a subpoena or voluntarily provided to OIG); and
- 5. Additional information, as part of its referral based on consultation with the appropriate agency, to the extent permitted by applicable law.

Health care provider actors may have the right to appeal administratively if the authority used to establish the disincentive provides for such an appeal. Additionally, the OIG will not render a final decision until all appeals have been completed. Transparency is a key component of the Disincentives Final Rule, with the ONC set to publicly post information about health care providers, information blocking practices, and applied disincentives on its website, but only after any appeals have been completed.

Key Takeaways:

In summary, the Disincentives Final Rule aims to deter information blocking through a comprehensive framework of disincentives that apply to a broad range of health care providers. These measures ensure that health care providers engage in practices that promote the access, exchange, and use of EHI, supporting better patient care and interoperability across the healthcare system. The following are some key takeaways for health care providers to consider:

- Broad Applicability: The disincentives will apply to a wide range of health care providers, including hospitals, skilled nursing facilities, home health entities, clinics, laboratories, and individual clinicians, but not all health care providers subject to the Cures Act at this time;
- More Disincentives Coming: HHS has requested public input to establish disincentives for all health care providers under the information blocking regulations and may introduce additional measures through future rulemaking:
- **Enforcement Start Date:** The OIG will not begin investigating health care providers until after the Disincentives Final Rule's effective date;
- Notice and Appeal Rights: Health care providers will be notified of any disincentives imposed and may have the right to appeal administratively. The OIG will not finalize decisions until all appeals are completed;
- Posting on ONC Website: The ONC will publicly post information about health care providers and disincentives applied, but only after any appeals have been completed; and
- No Retroactive Penalties: The disincentives will not apply to any conduct that occurred before the Disincentives Final Rule's effective date, ensuring that health care providers are only held accountable for future actions.

If you have any questions about the Disincentive Final Rule, information blocking, or need additional information regarding this alert, please contact Julie A. Kilgore or any member of the Baker Donelson Data Protection, Privacy, and Cybersecurity Team.

Hannah Moore, a summer associate at Baker Donelson, contributed to this article.