HHS Releases Long-Awaited Proposed Rule Regarding Appropriate Disincentives for Health Care Providers that Engage in Information Blocking

Insights 10.30.23

A new proposed rule released on October 30, 2023, by the U.S. Department of Health and Human Services (HHS) details the first steps taken by the Office of the National Coordinator for Health Information Technology (ONC) under the 21st Century Cures Act (Cures Act) to deter information blocking activities by health care providers.

Specifically, ONC proposes to establish disincentives for certain health care providers, including MIPS-eligible clinicians, ACOs, and certain eligible hospitals and critical access hospitals, determined to have engaged in information blocking by disqualifying them from benefits under existing programs administered by the Centers for Medicare & Medicaid Services (CMS). Enforcement by the HHS Office of Inspector General (OIG) – which is already in place for health IT developers, health information networks, and health information exchanges as of September 1, 2023 – would begin for health care providers subject to CMS's authority once the proposed rule becomes final.

This article summarizes a few key takeaways for health care providers, particularly those that are eligible to participate in the Medicare Promoting Interoperability Program, the MIPS Promoting Interoperability performance category (previously the EHR Incentive Programs), and the Medicare Shared Savings Program.

What is Information Blocking Again?

The Cures Act amended the Public Health Service Act (PHSA) in December 2016 to prohibit "information blocking" by certain actors, including a broad range of health care providers.[i] Information blocking is generally defined as a practice that is likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information. The PHSA also required HHS to identify reasonable and necessary activities that do not constitute information blocking. In March 2020, ONC released final rules governing information blocking and setting forth exceptions to the information blocking prohibition, each with detailed requirements that an actor must meet to avail itself of the exception.

Determination of Information Blocking by OIG

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Under the Cures Act, the OIG is authorized to investigate claims that "a health care provider engaged in information blocking." The proposed rule describes the process by which OIG would investigate a claim of information blocking by a health care provider and determine whether or not the provider committed information blocking. While OIG has discretion to choose which complaints to investigate, the proposed rule states OIG's expected focus will be on four priority areas, including alleged information blocking practices that: (i) resulted in, are causing, or had 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.

Following an investigation of an information blocking claim, if OIG determines that the health care provider had the requisite intent (i.e., the provider "knows that [the practice at issue] is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information") and did not meet an exception, OIG will then refer the determination to the "appropriate agency" to impose a disincentive.

The appropriate agency would be the agency administering the program under which a disincentive is imposed. In most instances, this would be CMS.

Proposed Appropriate Disincentives

After OIG refers a determination of information blocking to CMS, the proposed rule details the following appropriate disincentives the agency may impose for health care providers eligible to participate in the Medicare Promoting Interoperability Program, the MIPS Promoting Interoperability performance category (previously the EHR Incentive Programs), and the Medicare Shared Savings Program:

- **Medicare Promoting Interoperability Program:** A determination of information blocking by an eligible hospital or critical access hospital (CAH) that OIG refers to CMS would result in the eligible hospital or CAH not being a meaningful EHR user in an applicable EHR reporting period. For eligible hospitals, estimates provided in the proposed rule to illustrate the potential impact of the proposed disincentive show that this proposal could result in a median disincentive amount of $394,353 (although the disincentive's exact amount would depend on the hospital's Medicare payments).
- **Quality Payment Program:** Under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), an eligible clinician or group would not be a meaningful user of certified EHR technology in a performance period and would therefore receive a zero score in the Promoting Interoperability performance category of MIPS, if required to report on that category.
- **Medicare Shared Savings Program:** Under the Medicare Shared Savings Program, a health care provider that is an Accountable Care Organization (ACO), ACO participant, or ACO provider or supplier would be deemed ineligible to participate in the program for a period of at least one year. This may result in a health care provider being removed from an ACO or prevented from joining an ACO.

Following the application of a disincentive, a health care provider may have the right to an administrative appeal of a disincentive if the authority used to establish the disincentive provides for such an appeal.

The proposed rule does not limit the number of disincentives that an agency can impose on a health care provider – meaning that a health care provider could be subject to each appropriate disincentive that applies to that health care provider.

"Transparency" for Information Blocking Determinations

Finally, the rule proposes to establish a process by which information would be shared with the public about health care providers that OIG determines have committed information blocking in an effort to "promote transparency about how and where information blocking is impacting the nationwide health information technology infrastructure." In particular, ONC proposes to post on its website information regarding actors that have been determined by OIG to have committed information blocking, including the health care provider's name, business address, description of the information blocking

practice, and the disincentives applied.

What's Next?

The proposed rule leaves out many health care providers that are subject to the information blocking regulations but do not participate in any of the programs under which HHS is proposing to establish disincentives. Ultimately, ONC considers the proposed rule to be just a first step toward establishing disincentives for the broadest swath of health care providers furnishing services to Medicare beneficiaries and other patients. While there isn't a target publication date for future rulemaking on additional disincentives for health care providers, the proposed rule includes a request for information on additional appropriate disincentives that HHS should consider in future rulemaking, particularly for health care providers not impacted by the proposed disincentives.

On November 15, 2023, ONC and CMS will host an information session on the proposed rule. ONC is encouraging stakeholders to submit comments through regulations.gov, which are due by January 2, 2024, at 11:59 pm ET.

[i] Under 45 CFR 171.102 and 42 U.S.C. 300jj, the term "health care provider" refers to the following: a hospital; skilled nursing facility; nursing facility; home health entity or other long term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.

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