

# Breaking Down The Long-Awaited HHS Info Blocking Rule

By **Sara Shanti, Paul Werner and CJ Rundell** (August 15, 2023)

On July 3, the U.S. Department of Health and Human Services' Office of Inspector General published its much-anticipated final information blocking enforcement rule.[1]

Industry stakeholders have been eagerly awaiting this rule since the ONC for Health Information Technology set forth its final information blocking rules in 2020.[2]

The final enforcement rule provides clarity on the process and scope of enforcement and penalties for prohibited information blocking as well as conduct the OIG will prioritize for enforcement.

While this final rule provides weight behind the information blocking prohibitions, stakeholders will need to wait and see how the OIG implements its enforcement authority.

Understandably, the OIG noted that it has limited experience and information with regard to information blocking investigations and enforcement. Thus, its enforcement and guidance will evolve as it gains critical experience in assessing allegations, conducting information blocking investigations, and imposing penalties.

The OIG will need to learn to walk before it can run with enforcement.

The OIG enforcement rule is a step toward regulating conduct; however, there is still no rule for appropriate disincentives for provider-actors. As a result, there continues to be a lack of incentives for an entire category of information blocking actors to comply with the information blocking rules.

This leaves a significant enforcement gap for now, particularly given that the ONC received over four times as many information blocking claims against health care providers as it did for all other categories of potential actors combined from April 5, 2021, to June 30, 2023.[3]

## Scope

The OIG stated that while only health information networks, health information exchanges and developers of certified health IT are subject to the final rule at this time, health care providers will be subject to appropriate disincentives as they are defined in the coming months by HHS and the ONC.

The proposed rule for appropriate disincentives is scheduled to be published in September under the fall 2022 regulatory agenda.[4]



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## **Penalties**

The OIG's final enforcement rule provides a civil monetary penalty of up to \$1 million per violation.

A "violation" is defined as each practice that constitutes information blocking.

For example, the enactment of an internal policy — e.g., a policy whereby a health care provider withholds release of lab results to all patients pending provider review — that constitutes information blocking could be considered one violation, and each enforcement of the policy could constitute another separate violation, e.g., each time a health care provider withholds release of lab results to a patient until a provider has reviewed pursuant to its internal policy.

Based on this per-enforcement interpretation of a violation, actors could quickly accrue a number of violations, particularly for policies that actors enforce multiple times per day.

To the extent they have not already done so, actors should review their policies and procedures to ensure they are not likely to interfere with, prevent or materially discourage the access, exchange, or use of electronic protected health.

The OIG further clarified that its focus in determining the number of violations that occurred is on the specific action or actions of an actor, not on the number of patients affected.

In other words, an actor denying a single request to receive electronic health information for one patient would be one violation, as would an actor denying a single request to receive electronic health information for 10 patients.

## **Standards**

To decide whether to impose a civil monetary penalty and the amount of the civil monetary penalty, the OIG must consider factors such as the nature and extent of the information blocking, resulted harm, the number of patients and providers affected, and the duration of the blocking.

In addition, the OIG will apply the aggravating and mitigating factors in Title 42 of the Code of Federal Regulations, Part 1003.140 to the civil monetary penalty for information blocking determinations in a manner consistent with Section 1128A of the Social Security Act.

Such categories of aggravating and mitigation factors include, generally: (1) the nature and circumstances of the violation, (2) the degree of culpability of the actor, (3) the history of prior offenses, (4) other wrongful conduct, and (5) such other matters as justice may require.[5]

With regard to the OIG's consideration of the above aggravating and mitigating factors, it stated that such factors in the case of information blocking civil monetary penalties may include:

whether the practice actually interfered with the access, exchange, or use of EHI; the number of violations; whether an actor took corrective action; whether an actor faced systemic barriers to interoperability; to what extent the actor had control over the EHI; the actor's size; and the market share.[6]

Finally, the OIG declined to issue additional detail regarding the range of potential penalty amounts and the circumstances or thresholds that will trigger such penalty amounts, including any chart of facts and circumstances that would result in different penalty amounts, such as the chart provided by HHS for tiers of Health Insurance Portability and Accountability Act violations.[7]

In declining to do so, the OIG noted that setting civil monetary penalty amounts for individual information blocking violations requires a case-by-case evaluation wherein no formula will be followed.

### **Enforcement Process**

The OIG's enforcement will be complaint-based.

Upon receipt of a complaint, the OIG will assess whether to investigate or refer the complaint using its enforcement priorities and — if it determines appropriate — investigate the complaint.

The OIG set forth a number of enforcement priorities in its final rule, noting that it expects to receive more information blocking complaints than it can investigate.

The OIG will focus on prioritizing the following information blocking conduct when selecting cases for investigation:

- Resulted in, is causing, or had the potential to cause patient harm;
- Significantly affected a provider's ability to care for patients;
- Endured a significant duration;
- Caused financial loss to governmental programs or private entities; or
- Performed with actual knowledge.

With regard to patient harm priorities, the OIG is primarily focused on harm to a patient population.

As for its focus on practices performed with actual knowledge, which the OIG explicitly recognized is not a requirement for violations by health information exchanges, health information networks or developers under the ONC's rules, the OIG intends to prioritize cases in which an actor has actual knowledge over cases in which the actor only should

have known that the practice was likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information.

Further, the OIG anticipates that its enforcement priorities may lead to investigations of anti-competitive conduct or unreasonable business practices.

The OIG noted that the Public Health Service Act includes specific options for the ONC and the OIG to coordinate with the Federal Trade Commission related to an information blocking claim with anti-competitive conduct, including by sharing information, and that the OIG will coordinate with the ONC to identify claims and investigations that may warrant referral to the FTC.

In addition to the preceding priorities, the OIG may prioritize investigations based on the volume of information blocking claims relating to similar conduct by the same actor.

Finally, the OIG stated that it will add an information blocking self-disclosure protocol, including an online submission form and other processes, to its existing self-disclosure protocol.

The OIG noted the various benefits of using the self-disclosure protocol for information blocking violations, which potentially include paying lower damages than would normally be required and avoiding costs and disruption associated with a government-directed investigation or litigation.

The OIG specifically noted that disclosure via the protocol and full cooperation with the OIG's review and resolution of such a disclosure would be considered part of timely corrective action, which is a mitigating circumstance that the OIG will consider in determining the amount of a penalty.

### **Enforcement to Begin Sept. 1**

The OIG will begin enforcement starting on Sept. 1, 60 days after the final rule was published.

While health information exchanges, health information networks and developers have been required to comply with the ONC's information blocking rules for some time now, they have until the enforcement date to comply or be subject to penalties. Significantly, the OIG will not impose civil monetary penalties on information blocking conduct that occurred before Sept. 1.

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[1] 88 FR 42820 (Jul. 3, 2023).

[2] 88 Fed. Reg. 23746 (Apr. 18, 2023).

[3] <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>.

[4] <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA05>.

[5] 42 CFR 1003.140(a). The OIG further noted in its preamble that it must apply the provisions of section 1128A of the Social Security Act (regarding civil monetary penalties) (other than subsections (a) and (b) of such section) to a civil monetary penalty for information blocking in the same manner as such provisions apply to a civil monetary penalty or proceeding under section 1128A of the SSA.

[6] 88 FR 42820, 42833.

[7] 87 FR 15100, 15109 (Mar. 17, 2022).