

## Coppersmith Briefs

# OIG Releases Proposed Penalties for Information Blocking

[Melissa Soliz](#), Coppersmith Brockelman PLC  
April 27, 2020

On April 24, 2020, the Office of Inspector General for the Department of Health and Human Services (HHS) published the [proposed rule](#) for civil monetary penalties (CMPs) on information blocking in the Federal Register. **The comment period closes on June 23, 2020.** The proposed rule only addresses CMPs for information blocking by health IT developers or other entities offering certified health IT, health information exchanges (HIEs) and health information networks (HINs). It does not apply to health care providers who engage in information blocking and who do not meet the definition of a HIE/HIN.

### *A little background:*

The [21st Century Cures Act](#) (Cures Act) authorizes OIG to investigate claims of information blocking and gives HHS the authority to impose CMPs up to \$1 million per violation against health IT developers or other entities offering certified health IT, HIEs and HINs that engage in information blocking. HHS delegates to OIG the authority to impose CMPs.

The Cures Act defines information blocking as:

A practice that—(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and (B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

[42 USC § 300jj-52\(a\)\(1\)](#). The term does not include any conduct that occurred before January 13, 2017.

In March of 2020, the Office of the National Coordinator for Health Information Technology (ONC) released its [final rule on information blocking](#) (the ONC Information Blocking Rule). The ONC Information Blocking Rule sets out the substantive requirements for a finding of information blocking and the exceptions. The

compliance date for the ONC Information Blocking Rule is 6 months after its publication in the Federal Register. It is scheduled to be published in the Federal Register on May 1, 2020—setting a November 1, 2020 compliance date. However, OIG will exercise its enforcement discretion and not impose CMPs against actors who have engaged in information blocking until the proposed start of OIG’s enforcement, as set out below.

***What’s covered in OIG’s proposed rule:***

OIG proposes to:

- Delay enforcement of the ONC Information Blocking Rule until 60 days after publication of OIG’s final rule (OIG Final Rule) or, in the alternative, October 1, 2020. (The proposed alternative date is curious given that the compliance date for the ONC Information Blocking Rule will not occur until one month after this proposed alternative enforcement date.)
- Define a “violation” as each practice that constitutes information blocking, as defined by the ONC Information Blocking Rule. In determining the number of violations, OIG proposes to focus on the type of practice and not the number of patients affected. The number of patients affected would factor into the amount of the CMP. OIG gives several illustrative of examples of conduct that may give rise to a single violation versus multiple violations.
- Adopt the factors set out in the CURES Act for determining the CMP amount. The statutory factors are: (i) the nature and extent of the information blocking; and (ii) the harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

OIG seeks on comment on:

- When to start OIG enforcement, including why parties would need a longer or shorter time period to come into compliance with the ONC Information Blocking Rule.
- Its proposed approach to determining single versus multiple violations.
- Whether it should adopt additional aggravating and mitigating circumstances to adjust the CMP penalties.

OIG also provided some insight on its enforcement funding and priorities, such as:

- The FY 2021 President’s Budget proposes \$5.3 million for OIG information blocking activities.
- OIG will focus on conduct that results in, causes, or has the potential to cause patient harm; that significantly impacts a provider's ability to care for patients; is of long duration; causes financial loss to federal health care programs, or other government or private entities; or is performed with actual knowledge.
- OIG emphasizes that information blocking has an element of intent—knew or should have known for health IT developers or other entities offering certified health IT, HIEs and HINs—so that OIG will not bring enforcement actions against actors who made “innocent mistakes.”

However, OIG emphasized that these statements are nonbinding and do not impose any legal restrictions on OIG’s discretion.

With respect to health care providers, OIG further noted that:

If OIG determines that a health care provider has committed information blocking, it shall refer such health care provider to the appropriate agency for appropriate disincentives. The appropriate agency and appropriate disincentives will be established by the Secretary in future notice and comment rulemaking. OIG will coordinate closely with other agencies within HHS to develop consultation and referral processes consistent with such rulemaking by the Secretary. Further, in determining whether a health care provider has committed information blocking, OIG shall consider whether, in accordance with sec. 3022(a)(7), a developer of health information technology or another entity offering health information technology to such provider failed to ensure that the technology meets the requirements to be certified under the ONC Health IT Certification Program.

The proposed rule also sets forth OIG's proposal for adding new CMPs for fraud related to HHS grants, contracts, and other agreements, as well as increased maximum CMPs penalties for certain other violations enforced by OIG.

[Melissa Soliz](#) focuses on HIPAA and 42 C.F.R. Part 2 compliance, health information exchange and networks (including compliance with the new information blocking rule), compliance with opioid treatment laws and regulations, data breaches and OCR investigations, as well as clinical research compliance and contracting.

*By the way, you know the Coppersmith Briefs are not legal advice, right? Right!  
Check with your attorney for legal advice applicable to your situation.*