AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

June 23, 2020

Aaron S. Zajic
Supervisory Project Manager
Office of Inspector General
U.S. Department of Health and Human Services
Attention: OIG-2605-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Rule on Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules OIG-2605-P

Dear Mr. Zajic:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments to the Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules proposed rule ("Proposed Rule"). In particular, the Proposed Rule incorporates regulations recently published by the Office of the National Coordinator for Health Information Technology (ONC)[1] as the basis for enforcing information blocking civil money penalties (CMPs).

We appreciate the efforts of the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) to codify its responsibilities for information blocking enforcement while minimizing burdens on providers and being flexible where possible during the COVID-19 public health emergency. The COVID-19 pandemic has presented numerous challenges for the country as we navigate new pressures faced by both patients and providers as they seek to access patients' health information. You will find our comments and recommendations outlined in detail below.

Information Blocking Enforcement Time Frames

The Proposed Rule includes two potential effective dates for the enforcement of information blocking regulations. The first is 60 days after the publication of the OIG final rule; and the second is an alternate effective date for the OIG final rule of October 1, 2020. However, the Proposed Rule also states that "At a minimum, enforcement would not begin until the compliance date of the ONC Final Rule finalized at 45 CFR 171.101(b)," which is November 2, 2020. Accordingly, we anticipate that date to be the earliest effective date for the OIG final rule, even if the final rule is published more than 60 days prior to November 2.

[1] 45 CFR Parts 170 and 171, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, RIN 0955-AA01 ("ONC Final Rule").

We recognize that many stakeholders are eager for enforcement of information blocking to begin. The AMA is among those that advocated for many of the provisions included in the 21st Century Cures Act and is appreciative of a number of the policies advanced by ONC's final rule. We also appreciate that the Proposed Rule does not apply to health care providers, other than those that also meet the ONC final rule's definition of a health information exchange (HIE) or health information network (HIN). However, we note that those health care providers and entities that support them, such as health information technology (health IT) teams, remain under constant evolving threat of being overwhelmed by COVID-19. As of May 22, 2020, more than 120 days after the first case of COVID-19 was reported in the U.S., our country still leads the world in the number of new cases and deaths.[2] Moreover, because there is currently no viable treatment or vaccine for COVID-19, we expect that a second wave of COVID-19 may begin in the fall of 2020, coinciding with the seasonal flu and further straining the health care system, which may not yet have recovered from earlier in 2020.

As a result, **the AMA urges the OIG to align its final rule effective date with ONC's November 2, 2020, compliance date and to finalize no less than six months of discretionary enforcement. This framework "starts the clock" on enforcement while providing our health care system with a buffer as it recovers from the overwhelming pressure of the COVID-19 pandemic and the continued uncertainty posed by a likely second wave of the virus this fall and winter**. The OIG should use the discretionary enforcement period to prioritize education and corrective action over imposition of CMPs. Prioritizing education will be more effective over the long-term in ensuring compliance of all actors with the final ONC information blocking regulations, as they will better understand the regulatory requirements. We also note that this would comply with the recent Executive Order directing agencies not to over-enforce when a business is working in good faith to follow the law, which especially benefits small businesses fighting to recover from the impact of the pandemic.[3]

Approach to Information Blocking Enforcement

The AMA agrees with the OIG that "some individuals and entities subject to the information blocking CMPs may not be familiar with the OIG's enforcement authorities." Although the OIG explains its "anticipated approach to information blocking enforcement," including the agency's "expected priorities,"[4] the AMA is concerned that the enforcement priorities described in the Proposed Rule are "for information only," and are "not binding" on the agency. The OIG also notes that it "expects these priorities will evolve" as OIG gains more experience with investigating information blocking.[5] While we understand that the OIG may not be able to provide examples of every type of information blocking, the OIG's "informational only" enforcement approach and priorities and their impact on information blocking may prove challenging for stakeholders. **Enforcement should not begin without an increased level of**

[2] https://coronavirus.jhu.edu/data/new-cases.
[3] *Executive Order on Regulatory Relief to Support Economic Recovery*, May 19, 2020, available at https://www.whitehouse.gov/presidential-actions/executive-order-regulatory-relief-support-economic-recovery/.
[4] In the Proposed Rule, the OIG explains that its enforcement priorities are expected to include conduct that (i) "resulted in, is causing, or had the potential to cause patient harm," (ii) "significantly impacted a provider's ability to care for patients," (iii) "was of long duration," (iv) "caused financial loss to Federal health care programs, or other government or private entities," or (v) "was performed with actual knowledge." See Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules 85 Fed. Reg. 22984 (April 24, 2020) https://www.govinfo.gov/content/pkg/FR-2020-04-24/pdf/2020-08451.pdf.
[5] Id.

clarity from the OIG. Specifically, we seek additional guidance and accompanying resource materials on the following questions:

- Are the five expected priorities noted in the Proposed Rule equally weighted or are some more heavily weighted than others?
- How will the OIG evaluate "intent" in allegations of information blocking for investigation? We encourage the OIG, when possible, to provide examples of what an actor might do to demonstrate that it did not have the requisite intent, thus allowing actors to more soundly implement their programs to assure compliance with the information blocking requirements.
- What are examples of the types of "innocent mistakes" for which the OIG will not bring enforcement actions?
- Will health plans will be considered actors (e.g., as an HIE, HIN, or provider)?
- What factors will lead to providers being considered HIE/HINs?
- What factors will the OIG consider when determining if all an Actor's business units or service lines fall under the umbrella information blocking regulations based on an Actor offering only one "information blocking regulated" service? For instance, if an entity operates an HIN, as defined by ONC, while also offering services that would not constitute the entity as an Actor, will those non-HIN or -HIE services also fall into the purview of information blocking regulations?

The AMA is happy to help amplify the OIG's educational messages, but to do so properly we believe we need the additional clarification noted above.

In addition, we urge the OIG to consider the public availability of guidance clarifying the ONC Final Rule and, where such guidance is lacking, develop resources in consultation with ONC to help clarify its approach to information blocking enforcement.[6]

COVID-19 Factors for the OIG to Consider in Determining the Amount of Information Blocking CMPs

The AMA urges the OIG to consider as a mitigating circumstance, and as a basis for no or reduced CMPs, challenges faced by actors as a result of the COVID-19 pandemic and the associated national public health emergency declaration by the Secretary of HHS. Although this list is not exhaustive, such challenges may involve:

- The need to redeploy staff and resources from development or implementation of information blocking implementation and compliance plans to COVID-19 efforts. Over the next few months, some efforts to prepare for implementation and compliance that would have been otherwise underway are likely to be diverted to COVID-19 activities, both clinical and non-clinical;
- Reductions in available staff and resources as a result of furloughs and resource constriction (e.g., reduced clinical revenues) as a result of the COVID-19 emergency;
- Focusing interoperability and data access priorities on COVID-19, including support of initiatives like electronic case reporting, tracking testing, and other efforts to enhance patient and staff safety and quality of care; and

[6] https://www.healthit.gov/curesrule/.

- Challenges associated with an expected surge of patients as elective services resume in an environment that had shifted the focus to COVID-19 patients and furloughed clinical and non-clinical staff.

In addition, although we agree that the number of patients and providers affected is a reasonable factor in assessing CMP levels, we urge the OIG to ensure it is not creating a perverse incentive for information blocking against smaller entities (with fewer providers and patients) as opposed to larger entities, especially as the smaller entities, many of whom may be in rural or underserved areas, may have fewer resources to engage effectively with potential information blockers.

Applicability of Information Blocking CMPs to Health Care Providers

Although the Proposed Rule does not apply to health care providers who engage in information blocking,[7] health care providers that also meet the definition of a HIE/HIN as defined in the ONC Final Rule would be subject to information blocking CMPs. In the Proposed Rule, the OIG states, "[o]nce established, OIG will coordinate with, and send referrals to, the agency or agencies identified in future rulemaking by the Secretary that will apply the appropriate disincentive for health care providers that engage in information blocking, consistent with sec. 3022(b)(2)(B) [of the Public Health Service Act]."

We greatly appreciate the OIG's acknowledgement that while health care providers are generally not subject to information blocking CMPs, many must currently comply with separate statutes and regulations related to information blocking. As the OIG points out, since 2017, all Merit-based Incentive Payment System (MIPS) Eligible Clinicians who report on the Promoting Interoperability (PI) category are required to attest to three separate statements on information blocking. These attestations encompass knowledge or willful action on limiting or restricting interoperability; requirements on the implementation of technology (including EHRs) and technical standards to ensure interoperability; and responding to and providing patients and other individuals access to electronic health information (EHI). Physicians who fail to attest, or are information blockers, are subject to considerable financial penalties. Physician attestations are also publicly reportable on the Centers for Medicare & Medicaid Services' (CMS) Physician Compare website. Most physicians who do not participate in PI are still subject to the Health Insurance Portability and Accountability Act (HIPAA) requirements to provide patients or their designee access to their medical records. **We strongly support the OIG's consideration of current and well-established disincentives that discourage hundreds of thousands of physicians from information blocking.**

Furthermore, the AMA urges the OIG to initiate a work group that would allow the OIG to engage on a regular basis with multiple stakeholders, including health care providers or their representatives, as it develops disincentives for health care providers that engage in information

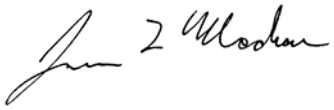
[7] "While health care providers are not subject to information blocking CMPs, many must currently comply with separate statutes and regulations related to information blocking. Prior to the enactment of the Cures Act, Congress enacted the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, which, in part, requires a health care provider to demonstrate that it has not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of Certified Electronic Health Record (EHR) Technology. To implement these provisions, the Centers for Medicare & Medicaid Services (CMS) established and codified attestation requirements to support the prevention of information blocking, which consist of three statements containing specific representations about a health care provider's implementation and use of Certified EHR technology (81 FR 77028 through 77035)." https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm.

blocking. The AMA believes that this work group would ensure that the OIG continues to obtain ongoing input from health care providers and other relevant stakeholders as the agency continues to develop policy in this evolving area.

Lastly, we encourage the OIG to prohibit actors from transferring liability for noncompliance with regulatory requirements onto the health care providers with whom they contract (e.g., health IT developers providing EHR services to physician practices should not be permitted to shift liability through contractual arrangements). Small and mid-size practices in particular are often presented with service contracts including undesirable terms on a "take it or leave it" basis; these practices may not have the market share or power necessary to negotiate with such service providers, or they may be in an area where only one service provider is available.

In closing, we greatly appreciate this opportunity to share our comments regarding the OIG's proposed rule. If you have any questions, please contact Matt Reid, Senior Health IT Consultant, Department of Federal Affairs, at matt.reid@ama-assn.org or 202-789-7419.

Sincerely,



James L. Madara, MD