



June 23, 2020

Aaron S. Zajic
Office of the Inspector General
US Department of Health and Human Services
Attention: OIG-2605-P
Cohen Building
300 Independence Avenue, SW
Room 5527
Washington, DC 20201

Re: Proposed Rule on *Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of the Inspector General's Civil Money Penalty Rules* (RIN 0936-AA09)

Submitted electronically at: www.regulations.gov

Dear Mr. Zajic:

Thank you for the opportunity to provide comments on the Office of the Inspector General's proposed rule, *Grants, Contract, and Other Agreements: Fraud and Abuse; Information Blocking; Office of the Inspector General's Civil Money Penalty Rules*.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide. Our general comments and specific recommendations related to certain sections of the proposed rule can be found below.

General Comments—Healthcare Providers

In general, we share OIG's belief that information blocking can pose a threat to patient safety and undermine efforts by providers, payers, and others to make our healthcare system more efficient and effective.

OIG states clearly that, as required under the 21st Century Cures (Cures) Act, the proposed rule only addresses imposition of civil monetary penalties (CMPs) for information blocking by health IT developers, or other entities offering certified health IT, health information exchanges, and health information networks and does not apply to healthcare providers that engage in information blocking. However, OIG also states that if it determines that a provider has committed information blocking, it shall refer the provider to the "appropriate agency for appropriate disincentives" which shall be established by the Secretary of HHS in future notice and comment rulemaking. OIG also states that it will

“coordinate closely with other agencies within HHS to develop consultation and referral processes consistent with such rulemaking by the Secretary. “

Given the absence of follow-on rulemaking to date by the Secretary, we are concerned as to how OIG will handle complaints of information blocking by providers until such subsequent rulemaking is completed. **Along these lines, we recommend that OIG, in its final rule, provide additional specificity as to how the agency intends to handle violations of information blocking by providers, including how violations will be referred to other agencies in keeping with the nonduplication of penalty structures as set forth in section 3022(d)(4) of the Public Health Service Act (PHSA).**

Subpart N – CMPs for Information Blocking

Enforcement Priorities

OIG states in the preamble of the proposed rule that its enforcement priorities will include conduct that: (i) resulted in, is causing, or had the potential to cause patient harm; (ii) significantly impacts a provider’s ability to care for patients; (iii) was of long duration; (iv) caused financial loss to Federal healthcare programs, or other government or private entities; (v) or was performed with actual knowledge. We recognize that these priorities are not binding on OIG and that the agency intends these priorities to evolve as OIG gains more experience in investigating information blocking. **However, additional clarity around whether these priorities will be equally weighted in terms of priority would help ensure that HI professionals focus their attention on addressing the most critical concerns as it relates to information blocking.**

Intent

OIG states in the proposed rule that information blocking requires an element of intent, as set forth under the Cures Act, and therefore the agency lacks the statutory authority to pursue enforcement actions against actors that make “innocent mistakes.” **We appreciate OIG’s proposed approach set forth under the proposed rule, however, we recommend that as part of the final rule, OIG include examples of when requisite intent may be lacking (i.e.—“innocent mistakes”).** We believe such illustrative examples will help actors ensure that their information blocking compliance plans are consistent with what is required under the law.

Effective Date of Enforcement

AHIMA supports OIG’s proposal that the effective date of the regulations be 60 days from the date of publication of the OIG final rule as well as its intention to only exercise its enforcement discretion against actors engaging in information blocking after the effective date of the rule. We agree that the period between the compliance date of ONC’s Final Rule, (November 2, 2020) and the proposed effective beginning of OIG’s information blocking enforcement provides sufficient time for actors to come into compliance with the ONC Final Rule and offers additional certainty to actors that their practices during this period will not be subject to CMPs. We believe this is particularly important in light of the ongoing COVID-19 public health emergency. In the last few months, many health information professionals have experienced a change in job status, suffered new resource constraints, or been diverted to COVID-19-related activities, making it difficult to plan for implementation and compliance with the ONC Information Blocking Rule. We believe OIG’s proposal to delay the effective date of the regulations 60 days from date of publication of the final rule and OIG’s intention to not begin

enforcement until after the effective date of the final rule will provide much-needed flexibility and assistance to actors seeking to comply with the ONC Information Blocking Rule.

Basis for Civil Monetary Penalties

AHIMA agrees with OIG's proposed approach to subject any CMP determination based on an investigation of information blocking to the CMP procedures and appeals process in 42 CFR parts 1003 and 1005. We believe such an approach offers predictability to HI professionals already familiar with existing CMP processes and could alleviate additional burden related to compliance with the rule.

We appreciate the opportunity to submit comments on OIG's proposed rule and we look forward to working with you to ensure its successful finalization and implementation. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President of Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,

A handwritten signature in cursive script that reads "Wylecia Wiggs Harris".

Dr. Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA