



June 23, 2020

Christi Grimm
Principal Deputy Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5527
Washington, DC 20201

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

Dear Principal Deputy Inspector General Grimm,

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the *Fraud and Abuse; Information Blocking; Office of Inspector General's (OIG's) Civil Money Penalty Proposed Rules*. ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College is supportive of the Department of Health and Human Services' (HHS) efforts, through coordination across the various agencies, including OIG, the Office of the National Coordinator for Health IT (ONC), and the Centers for Medicare and Medicaid Services (CMS), to improve interoperability of and patient access to electronic health information. We agree these efforts are integral to improving patient-centered, value-based health care; however, as we noted in our comments¹ to ONC on their proposed rule, we remain concerned regarding the downstream and likely burdensome effects the information blocking provisions and compliance requirements will have on day-to-day physician practice. While we understand OIG's

¹ ACP Comments to ONC regarding Interoperability and Information Blocking Proposed Rule (May 2019): https://www.acponline.org/acp_policy/letters/acp_comments_onc_proposed_rule_interoperability_information_blocking_2019.pdf

enforcement and penalties do not apply to physicians and other clinicians, OIG will still be tasked with investigating certain information blocking claims related to physicians, and referring those claims to the relevant agencies for disincentives that will be outlined in future rulemaking. Therefore, ACP recommends OIG take the following recommendations into consideration when finalizing the proposed regulation.

Additional Clarification on Assessing Information Blocking Claims

The College remains concerned that understanding how the complex information blocking provisions and exceptions will affect our physician members in their daily practice will prove to be extremely complicated. With each information blocking claim or exception being reviewed subjectively, based on the facts and circumstances of each case, by varying agencies under HHS, there is a lack of clarity on what physicians will be required to implement and document in order to effectively comply with the information blocking provisions. ACP appreciates OIG's overview and discussion around the factors determining enforcement of information blocking penalties, including the nature and extent of information blocking as well as the need for requisite intent. Additionally, the College appreciates OIG's experience in investigating other types of fraudulent or improper activities within HHS, and the importance of OIG enforcement discretion; however, we believe this discretion must be balanced with clear regulatory language or guidance around how and what types of information blocking claims will be assessed.

Therefore, ACP recommends OIG, in coordination with ONC and the Office of Civil Rights (OCR), develop clear guidance materials providing physicians with a baseline for what is required to comply with the additional health data requests that will accompany these important interoperability regulations to ensure physicians are not inadvertently blocking information. This additional guidance and/or educational resources should also include examples of the types of documentation needed should physicians be subject to an information blocking claim or investigation.

Enforcement Date and Educational Period

In order to meet these new information blocking requirements outlined by ONC, it will take a significant amount of time and resources to develop and implement internal policies around the types of application programming interface (API) queries the health system or physician practice will allow into their system. An additional and important element of this compliance will be to make sure physician practices are able to appropriately document or record that they took the necessary steps to share electronic health information appropriately and are not accidentally blocking information, or included in an information blocking claim that is not within their control. This burden will disproportionately disadvantage independent physician practices as they likely do not have the resources to employ information security or health information management departments to assist them in deciphering the regulations and overlaps with existing privacy and security regulations. These concerns do not even take into account the current COVID-19 pandemic and toll it is taking on the population and healthcare system – as well as physicians' capacity to implement these compliance requirements while working to address the national public health emergency. **For these reasons, ACP recommends OIG, in**

coordination with the other HHS agencies responsible for information blocking enforcement relevant to physicians, allow for graduated enforcement that includes an initial education period for physicians. This educational period should focus on assessing the information blocking claims received to better understand real-world information blocking scenarios and implications on physician workflows. At a minimum, the official enforcement date for physicians, after the educational or pilot period, should be no sooner than one year after the ONC compliance deadline for information blocking, or November 2021.

As OIG works to finalize these proposed rules, we hope you will consider our feedback and continue to engage with our organization and the broader stakeholder community in future deliberations. Should you have any questions, please contact Brooke Rockwern, Senior Associate for Health IT Policy and Regulatory Affairs, at brockwern@acponline.org.

Sincerely,

A handwritten signature in blue ink, appearing to be 'ZAR', written over a light blue horizontal line.

Zeshan A. Rajput, MD, MS
Chair, Medical Informatics Committee
American College of Physicians