

June 19, 2020

Aaron S. Zajic  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-2605-P  
330 Independence Avenue, SW, Room 5527  
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 RIN 0936-AA09***

Dear Mr. Zajic:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed rule on grants, contracts, and other agreements: fraud and abuse; information blocking; Office of Inspector General's (OIG) civil money penalty (CMP) rules.

**The AHA concurs with OIG that information blocking “can pose a threat to patient safety and undermine efforts by providers, payers, and others to make our health system more efficient and effective.”** Hospitals and health systems across the country have implemented robust capabilities in recent years to share health information among providers and with patients to improve care coordination, more fully engage patients in their care and support better health outcomes.

The ongoing COVID-19 public health emergency (PHE) highlights the critical importance of ensuring health information is available where and when it is needed to inform patient care decisions. At the same time, preparing for and responding to COVID-19 also has placed great [financial strain](#) on hospitals and health systems. According to an AHA analysis, hospitals and health systems are projected to lose more than \$200 billion between March 1 and June 30 due to the pandemic. Compliance with the Office of the National Coordinator for Health Information Technology (ONC) final rule on interoperability, information blocking and the ONC health information technology (IT) certification program will require significant



effort to analyze and update internal processes and procedures, implement necessary changes to technology platforms and address related operational issues at a time when resources must continue to be prioritized for patient care. The current lack of guidance and clarity on many key provisions of the ONC interoperability final rule also will present a challenge for the planning and implementation efforts necessary to achieve compliance.

With these considerations in mind, the AHA offers the following comments on the information blocking provisions of OIG's proposed rule.

**Treatment of Actors.** Congress created a clear distinction in the 21<sup>st</sup> Century Cures Act between health care providers and health information exchanges (HIEs), health information networks (HINs) and IT developers by establishing different sanctions for each group of actors – “appropriate disincentives” for providers and CMPs for HIEs, HINs and IT developers. Section 3022(b)(2)(B) of the Public Health Service Act provides that any health care provider determined by OIG to have committed information blocking shall be referred to the “appropriate agency to be subject to appropriate disincentives” determined by the Health and Human Services (HHS) Secretary through notice and comment rulemaking. Congress additionally included language stating that penalties imposed related to information blocking should not be duplicative with penalties imposed under other parts of the law as well as under OIG's authority to impose CMPs.

Consistent with congressional intent, OIG recognizes that the proposed CMP rule does not apply to health care providers. Unfortunately, ONC's overly broad drafting of the definition of an HIE/HIN established in the final rule failed to carry through the distinction Congress made between health care providers and third-party entities whose primary business model is to facilitate information exchange among external parties.

The ONC final rule defines an HIE/HIN as an individual or entity that determines, controls, or has the discretion to administer any requirement, policy or agreement that permits, enables, or requires the use of any technology or services for access, exchange or use of electronic health information: (1) among more than two unaffiliated individuals or entities that are enabled to exchange with each other; and (2) that is for a treatment, payment or health care operations purpose as defined in 45 CFR 164.501.

While hospitals and health systems often perform this type of function for purposes of care coordination or as part of their participation in an alternative payment model, such as an accountable care organization (ACO), they do so in their capacity as health care providers. Similarly, health systems also can provide enterprise services to electronically exchange clinical information among providers using different electronic health records (EHR) platforms.

**Health care providers are not third parties and should not be treated as such. If an entity's primary role is as a health care provider, and it is acting in that capacity to perform information exchange functions in support of patient care, that entity should not also be considered a different type of actor. The AHA urges OIG to apply this**

**critical distinction as it exercises its authority to investigate information blocking and impose CMPs.**

**Enforcement Timeline.** The proposed rule offers two potential approaches to establishing an enforcement date for information blocking – a date certain, such as Oct. 1, 2020 or a period after publication of the final rule, such as 60 days. The AHA urges a different approach based on two key factors that will affect the ability of hospitals to be in compliance: the availability of increased clarity and guidance related to the ONC interoperability final rule and the impact of the ongoing COVID-19 PHE.

OIG acknowledges that “information blocking is newly regulated conduct.” **Based on the lack of existing guidance to assist actors in operationalizing the ONC final rule and the significant challenges related to the ongoing COVID-19 PHE, the AHA recommends that formal enforcement not begin for actions that occur before a date of six months after publication of the OIG final rule or a date of six month after the end of the PHE declaration, whichever is later.**

We further ask that OIG provide additional clarity on the relationship between the effective date that will be established via this rule and the Nov. 2, 2020 compliance date in the ONC interoperability final rule. There is significant uncertainty regarding how OIG will handle investigations and possible referrals to other agencies of information blocking by health care providers, particularly in the period prior to completion of follow-on rulemaking by the HHS Secretary.

**Additional Clarification.** Given that the statutory definition of information blocking includes an element of intent, **we request OIG provide examples that illustrate the difference between knowledge of information blocking, on the one hand, and a “mistake,” on the other, that would not bring about enforcement actions, either under the CMPs or by referral to another agency in the case of health care providers.** This additional clarity will aid health care providers in developing implementation and compliance programs to prevent information blocking within their organizations.

We appreciate the opportunity to comment. Please contact me if you have questions or feel free to have a member of your team contact Samantha Burch, director of health information technology policy, at [sburch@aha.org](mailto:sburch@aha.org) or 202-626-2313.

Sincerely,

/s/  
Melinda Reid Hatton  
General Counsel