

## **Comment Letter to the Office of Inspector General Technology on Information Blocking Civil Money Penalty Proposed Rule**

June 23, 2020

The Honorable Christi A. Grimm  
Principal Deputy Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

Submitted electronically via: <https://www.federalregister.gov/documents/2020/04/24/2020-08451/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector>

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

Dear Ms. Grimm,

On behalf of the [Strategic Health Information Exchange Collaborative \(SHIEC\)](#), which represents more than 70 health information exchanges and health information networks (HIEs and HINs) across the nation, we are pleased to submit our comments on the Office of Inspector General's (OIG) Civil Money Penalty (CMP) proposed rule.

As the unbiased, vendor-neutral data trustees for their communities, SHIEC member HIEs serve nearly 92% of the United States population and are critical to achieving better health and quality of life in America. HIEs uniquely provide community-level identity resolution and linking of data beyond certified electronic health record systems, including data from pharmacies, post-acute care, behavioral health, social services, and many others. The dedication, energy, and passion exhibited by SHIEC's member HIEs over the past 20+ years have laid the foundation for nationwide health data interoperability in our communities and regions.

### **Comments on Subpart N – CMPs for Information Blocking**

#### **1. Effective date and enforcement date of information blocking CMP regulations**

As OIG notes in the proposed rule, some individuals, and entities subject to information blocking CMPs may not be familiar with OIG's enforcement authorities. These entities, including information blocking actors as defined in the Office of the National Coordinator for Health IT's (ONC) 21<sup>st</sup> Century Cures Act ("Cures Act") final rule, are in the process of updating technological capabilities, policies, and procedures to comply with the provisions of the final rule, while also responding to the COVID-19 pandemic.

**Therefore, we believe that effective date of subpart N of part 1003 should align with the compliance date of November 2, 2020 of the ONC Cures Act final rule. Additionally, we believe that OIG should extend an additional 3-month COVID-19 pandemic enforcement discretion to information blocking enforcement under this proposed rule.** This would mean that OIG would begin enforcement of information blocking CMP regulations on February 2, 2021, in line with ONC's already-extended enforcement discretion for the provisions of 45 CFR Part 170. We believe that a fixed, aligned date for enforcement is important for individuals and entities subject to information blocking CMPs to appropriately plan and prepare for compliance.

During this period, we encourage OIG to engage the community in the advisory process to provide meaningful and needed advice on the application of the information blocking rule and CMP regulations to specific factual situations.

*2. Definition of a "violation" as each "practice" that constitutes information blocking*

Generally, we support the definition of an information blocking violation as a "practice" (from the ONC final rule at 45 CFR 171.102 as "one or more related acts or omissions by an actor") that constitutes information blocking. However, we believe that OIG should provide more clarity in the final rule on violations regarding an act or omission for a single patient record versus an act or omission for multiple patient records in a single request. **Specifically, more detailed examples are needed to determine when an act or omission is a single violation or multiple violations with distinct practices.**

SHIEC member HIEs and the providers they partner with are often subject to pervasive information blocking business practices when requesting connectivity on behalf of providers or patients. We have compiled the following examples from some of our member HIEs:

- Implementation projects with rural and smaller, community-based providers often fail or stall because their Electronic Health Record (EHR) vendors assess hefty fees to establish connectivity with HIE networks. Often these fees amount to more than SHIEC member HIE fees assessed for services, doubling, or tripling the cost of connection for these providers.
- Some EHR vendors do not adequately filter or segment data, which results in information blocking. For example, if a patient has substance abuse treatment services under 42 CFR Part 2 that is subject to additional consent to share, some EHR vendors will block the entire health record, and not just the Part 2 content, because they cannot filter the Part 2 data from the rest of the clinical record.
- EHRs often limit providers to only one external connection to an HIE, HIN, or an ACO, although they often need to connect to multiple networks to appropriately coordinate care.

The HIE/HIN community would benefit from further clarity regarding whether the practices detailed above would constitute a single violation or multiple violations.

3. Additional factors to consider in determining the amount of information blocking CMPs

**We believe that there are mitigating circumstances which should be used to adjust information blocking CMPs, in addition to those proposed by OIG.** The regulation and enforcement of information blocking is new, both to OIG and to potential information blocking actors, and experience and time will likely require future rulemaking or guidance from OIG to identify additional factors and determine the appropriate CMPs. Additional mitigating factors we have identified are as follows:

- **Contributory practices.** Did the acts or omissions of another individual or entity (regardless of whether they are an information blocking actor as defined in the ONC Cures Act final rule) contribute to the act or omission of information blocking?
- **Financial condition.** Did the entity have financial difficulties affecting its ability to comply with the information blocking regulations, or will CMPs jeopardize its ongoing ability to support the effective exchange of electronic health information? For instance, many HIEs and HINs are operated by non-profit organizations or state agencies. These HIEs/HINs are critical to the exchange of electronic health information in many of the communities that they serve, and often provide services at a low or no cost to small community providers. The continued viability of these organizations and the important services that they provide should be considered when considering whether to impose CMPs and the amount.
- **Past practices.** Does the actor have a history of compliance with the information blocking regulations (e.g., whether it's a first-time violation, the same or similar violation has occurred in the past, and remediation efforts for prior noncompliance). OIG should have discretion to not impose CMPs or to reduce the amount if the HIE/HIN is a first-time offender and/or if the violation would be better addressed through technical guidance as opposed to financial penalty.

4. Disincentives for providers who engage in information blocking acts or omissions

We understand that the OIG proposed rule only addresses OIG's imposition of CMPs for information blocking by health IT developers, HIEs, or HINs, and that it does not apply to most health care providers who engage in information blocking. OIG states that it will coordinate with and send referrals to the agency or agencies identified in future rulemaking by the Secretary, who has the authority to apply appropriate disincentives, per statute.

**However, effective enforcement of information blocking must include all potential actors.** We urge OIG to work with the Secretary and the agency or agencies to be identified to promulgate rulemaking in this area.

5. OIG investigations of information blocking complaints

Many HIEs/HINs are unfamiliar with the OIG investigation process generally and have many questions about how the investigation process will work for claims of information blocking specifically. We request that OIG provide the community with an explanation of the OIG investigation process, procedures, and OIG expectations of actors under investigation. We further request additional guidance on the types of “innocent mistakes” referenced in the proposed rule that will not trigger investigation or enforcement actions.

Transparency and clarity in the investigation process will help the community to ensure that the intended goals of the information blocking rule are met.

We appreciate the opportunity to comment on the proposed rule. For follow-up questions or resources about SHIEC’s membership, please contact SHIEC’s CEO Kelly Thompson at [kelly.thompson@strategichie.com](mailto:kelly.thompson@strategichie.com).

A handwritten signature in black ink that reads "Kelly Hoover Thompson". The signature is written in a cursive style with a large initial "K".

Kelly Hoover Thompson  
CEO