



June 3, 2020

Aaron S. Zajic
Office of Inspector General
Department of Health and Human Services
Attention: OIG-2605-P
Cohen Building
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

Submitted electronically at <http://www.regulations.gov>

Dear Mr. Zajic:

The Sequoia Project is pleased to submit these comments on the Proposed Rule on *Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's (OIG) Civil Money Penalty Rules*. Our comments focus on the amendment by the 21st Century Cures Act (Cures Act) of the Public Health Service Act (PHSA), 42 U.S.C. 300jj-5, authorizing the OIG to investigate claims of information blocking and providing the Secretary (Secretary) of Health and Human Services (HHS) authority to impose Civil Monetary Penalties (CMPs) for information blocking.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth Exchange and Carequality now operate under their own non-profit organizations. The Sequoia Project currently supports the RSNA Image Share Validation Program, the Patient Unified Lookup System for Emergencies (PULSE), and the Interoperability Matters Cooperative. Lastly, we are honored to have been selected by the Office of the National Coordinator for Health IT (ONC) to be the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA).

These comments reflect our experience supporting large-scale, nationwide health information sharing, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability. Our deep experience implementing national-level health IT interoperability, including our track record

of supporting and operationalizing federal government and private sector interoperability initiatives, provide a unique perspective on the proposed rule.

More directly, these comments reflect the expert input of the Information Blocking Workgroup of the Sequoia Project's Interoperability Matters Cooperative. This multi-stakeholder workgroup has been in place for over a year and has developed detailed comments and analysis of the ONC information blocking proposed and final rules.

Overall Perspectives

We appreciate the efforts of OIG to codify its responsibilities for information blocking enforcement and the conciseness of its proposed regulatory text. We share an overall aim to improve the health and health care of patients and our nation through more seamless patient and provider access to patients' health information. As OIG looks to finalize this proposed rule, we urge you to consider the attached perspectives of the Information Blocking Workgroup, especially on areas in guidance or regulatory language that would be benefit from further clarification.

These perspectives focus on:

- OIG investigative criteria;
- Approaches for the effective date of OIG's information blocking CMP regulations;
- Incorporation of information blocking regulations into 42 CFR part 1003 and application of current CMP procedures and appeal process to information blocking CMPs;
- Regulatory language to codify the maximum OIG penalty per information blocking violation;
- Examples of single and multiple violations and the definition of "violation"; and
- Additional factors to consider in determining the amount of information blocking CMPs, including examples of conduct that should be subject to higher or lower penalty amounts

Healthcare Providers

OIG acknowledges that health care providers are not subject to the imposition of Civil Money Penalties under the Cures Act and, therefore, the proposed rule is not applicable to health care providers. However, OIG also states that, per the Cures Act, it will determine whether a health care provider has committed information blocking and refer such cases to "the appropriate agency for appropriate disincentives". Lastly, OIG further states that once a process is established through a forthcoming notice and comment rulemaking as required by the Cures Act, "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".

It is our experience that there is significant uncertainty in the provider community, and other communities, about how OIG will handle complaints it receives about potential information

blocking by providers, especially before completion of the referenced follow-on rulemaking. We urge OIG, as it finalizes this current proposed rule, to be explicit on how it will handle complaints of provider information blocking, including whether these will be referred to other agencies. This clarification should also address the role of OIG, if any, in enforcement related to CMS provider attestations that relate to behavior that could be considered information blocking.

Conclusions

We appreciate the opportunity to provide you our comments on the information blocking provisions of OIG's proposed rule regarding its plans to investigate claims of information blocking and to apply Civil Monetary Penalties for information blocking. The Sequoia Project stands ready to assist you in any way that we can.

Most respectfully,

Mariann Yeager
CEO, The Sequoia Project

Attachment

Appendix: Perspectives on *Subpart N - CMPs for Information Blocking of the Information Blocking Workgroup of The Sequoia Project's Interoperability Matters Cooperative*

1. Approaches for the effective date of OIG's information blocking CMP regulations

- We believe that the primary OIG proposal, to base the enforcement date on a fixed period (e.g., 60 days) after final rule publication, makes the most sense. We urge OIG to further clarify the interrelationship of its enforcement date with the compliance date set by the publication date of the ONC Final Rule. There will be inevitable confusion and uncertainty as enforcement timing appears to be driven by the interrelated publication dates of two final rules, one not yet published from OIG and one already published from ONC (with a November 2, 2020 compliance date).
- In addition, we urge that OIG ultimately finalize its enforcement date (i.e., final decision on fixed period after OIG Final Rule publication) considering the actual and anticipated availability of increased clarity and guidance on material issues related to the ONC Final Rule. We have identified, and in many cases shared with ONC, continuing areas of uncertainty within the community, for example the extent to which health plans could be considered information blocking actors (e.g., as an HIE/HIN or provider) as well as whether and when actors like providers can be considered an HIE/HIN. **Enforcement should not begin without much more clarity than now exists.**
- In addition, in determining the OIG enforcement date, in addition to the challenges posed by continued industry uncertainty, it is important for OIG to consider the profound COVID-19-related impacts detailed in Comment #6 below. As a result, some members of the Workgroup have suggested that formal enforcement and imposition of CMPs not begin for actions that occur before a date six months after publication of the OIG Final Rule, with the period between two months and six months after publication used for an OIG advisory process with actors, using real-world examples.

2. Incorporation of information blocking regulations into 42 CFR part 1003, and application of CMP procedures and appeal process in parts 1003 and 1005 to information blocking CMPs

- The proposed regulatory codification of the information blocking regulations seems appropriate, as does the application of existing CMP and appeals processes. The latter will enhance compliance by organizations, attorneys, and compliance professionals already familiar with OIG CMP processes.

3. Regulatory language to codify the maximum OIG penalty per information blocking violation

- The proposed regulatory language is appropriate given the explicit Cures provisions for maximum penalties.

4. Guidance on how the OIG would decide which allegations it will investigate

- We understand that OIG reserves the sole authority to decide which allegations of information blocking it will investigate, but this does create significant uncertainty for those who believe they have faced information blocking as well as those Actors developing implementation and compliance plans. Since the information blocking rule does not provide a private right of action, the investigation of complaints by OIG is an essential remedy for such parties and a critical compliance issue for Actors.
- The narrative in the proposed rule preamble identifies five factors that OIG will consider in initiating investigations, but it would be very helpful if OIG could indicate in the final rule whether these five factors are equally weighted or whether some are more heavily weighted. For example, is evidence of patient harm more likely to result in an OIG investigation than is a practice that was of long duration but did not result in patient harm. This is simply an example, but additional clarity would be extremely helpful.
- We also request that OIG provide more specific guidance in its final rule and accompanying materials on how it will evaluate “intent” in allegations of information blocking for investigation. If possible, examples of what an Actor might do to demonstrate that it did not have the requisite intent would help Actors implement their programs to assure compliance with the information blocking requirements. Additionally, it would be helpful if OIG could provide examples of the types of “innocent mistakes” for which it will not bring enforcement actions.

5. Examples of single and multiple violations and definition of “violation”

- In general, we agree that it makes sense to define a “violation” as a “practice” as defined in the ONC Final Rule. At the same time, as illustrated by the need for OIG to provide examples of single and multiple violations, and the general and high-level ONC definition of a “practice” as “an act or omission by an actor, that constitutes information blocking, as defined in 45 CFR part 171,” we urge OIG to codify in its final regulations more specific bases for identifying single vs. multiple acts or omissions, reflecting its helpful preamble text and finalized examples. In particular, the regulatory text should provide a firmer guide to when an act or omission for a single patient or a single request by a data requester (but affecting multiple patients) would qualify as a single violation and when a violation includes multiple discrete practices.
- In addition, we appreciate OIG’s statement in preface to these examples that “[a]s with the prior examples, these examples assume that the facts meet all the elements of the information blocking definition, which includes the requisite level of statutory intent, are not required by law, and do not meet any exception established by the ONC Final Rule”. It would be helpful if each such example in the Final Rule specifically notes that an applicable exception does not apply (e.g., the Security exception for vetting), as such examples may be used by the community in a context and format that does not include this general statement about exceptions.

6. Additional factors to consider in determining the amount of information blocking CMPs, including examples of conduct that should be subject to higher or lower penalty amounts

In general, OIG's factors make sense, and we have the following suggestions:

- First, we urge 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 declared federal emergency. Such challenges could 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
 - 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.
- Second, some Workgroup members have emphasized that information blocking that hinders COVID-19 responses (and meets thresholds for intent, impact, lack of an applicable exception, compliance with current law, etc.) should likely receive higher CMPs than information blocking with other impacts, reflecting the above factors as well as the importance of electronic health information to timely and effective COVID-19 prevention, mitigation, and care.
- Finally, although the number of patients and providers affected is a logical factor in assessing CMP levels, we urge OIG to also take great care to avoid creating de facto incentives 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.