

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.
- 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.**

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 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 the 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.

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;
 - 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.
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- Second, information blocking that hinders COVID-19 responses (and meets thresholds for intent, impact, lack of an applicable exception, 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.
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- 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.